Regulatory Analysis Form

(Completed by Promulgating Agency)

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INDEPENDENT REGULATORY REVIEW COMMISSION

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Independent Regulatory Review Commission

June 4, 2026

(1) Agency

Health

(2) Agency Number: 10

Identification Number: 242

IRRC Number: 3490

(3) PA Code Cite: 28 Pa. Code Chapter 27

(4) Short Title: Communicable and Noncommunicable Diseases

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(6) Type of Rulemaking (check applicable box):

- ☒ Proposed Regulation
- ☐ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

This proposed rulemaking contains much needed amendments to existing regulations at 28 Pa. Code Chapter 27 (relating communicable and noncommunicable diseases). Comprehensive amendments to the regulations are needed to expand the list of reportable diseases, infections and conditions, to address changing standards and recommendations from experts, such as the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP), and to ensure the overall public health and safety by reducing the risk and spread of diseases, infections and conditions.

(8) State the statutory authority for the regulation. Include specific statutory citation.

Section 16(a) of the Disease and Prevention Control Law of 1955 ("Act") (35 P.S. § 521.16(a)) gives the State Advisory Health Board (Board) the authority to issue rules and regulations on the following: (1) the communicable and noncommunicable diseases that are to be reported; (2) the methods of reporting of diseases, the contents of reports and the health authorities to whom diseases are to be reported; (3) the communicable diseases which are subject to isolation, quarantine, or other control measures; (4) the duration of the periods of isolation and quarantine; (5) the enforcement of isolation and vaccination of persons and animals; (6) the immunization and vaccination of persons and animals; (7) the prevention and control of disease in public and private schools; (8) the regulation of carriers; (9) the advertisement of treatment, prophylaxis, diagnosis and cure of venereal diseases and the information which the physician must convey to persons being treated for a venereal disease in a communicable stage; (10) the prevention and control of noncommunicable diseases; and

(11) any other matters it may deem advisable for the prevention and control of disease and for carrying out the provisions and purposes of the Act. Section 16(b) of the Act (35 P.S. § 521.16(b)) gives the Secretary of the Department the authority to review existing regulations and make recommendations to the Board for any changes the Secretary deems to be desirable.

The Department also has the general duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 ("the Administrative Code") (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code (71 P.S. § 532(g)) for this purpose. Section 2111(b) of the Administrative Code (71 P.S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease and for the protection of the lives and the health of the people of this Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department. Section 2106(a) of the Administrative Code (71 P.S. §536(a)) also provides the Department with authority to declare diseases to be communicable, and to establish regulations for the prevention and control of disease. Section 2106(b) of the Administrative Code (71 P.S. § 536(b)) gives the Department the authority to establish and enforce quarantines to prevent the spread of diseases declared by law or by the Department to be communicable diseases. Section 2106(c) of the Administrative Code (71 P.S. § 536(c)) gives the Department the authority to administer and enforce the laws of this Commonwealth with respect to vaccination and other means of preventing the spread of communicable diseases.

The Board is required under section 2111(c.1) of the Administrative Code (71 P.S. § 541(c.1)) to make, and revise from time to time, a list of communicable diseases against which children shall be required to be immunized as a condition of attendance at any public, private, or parochial school, in this Commonwealth. This list shall be promulgated by the Secretary along with such regulations as may be necessary to ensure that such immunization be timely, effective and properly verified. Section 1421(c)(2) of the Public School Code of 1949 ("Public School Code") provides that the Secretary of Health, in consultation with the Secretary of Education, has the authority to promulgate regulations implementing the school health program. The requirements for the school health program are set forth in Article XIV of the Public School Code, and provide, among other things, that pupils are to be released from compulsory attendance when prevented from attending school by the laws or regulations of this Commonwealth. (24 P.S. § 14-1417). Section 1303a of the Public School Code (24 P.S. § 13-1303a) also requires school directors, superintendents, principals and other persons in charge of a school to ascertain that children, prior to admission to school for the first time, have been immunized against diseases listed by the Department, and reviewed by the Board. Regulations pertaining to vaccination of school age children exist primarily in 28 Pa. Code, Chapter 23. However, there is some overlap with these regulations in existing § 27.77 (relating to immunization requirements for children in child care group settings), which the Department proposes to amend.

The Newborn Child Testing Act established a program within the Department to provide for screening tests of newborn children and follow-up services for certain diseases and conditions in the newborn child. (35 P.S. § 623). The Department has the authority, with the approval of the Newborn Screening and Follow-up Technical Advisory Board, to make changes to the reportable list of diseases and conditions under that act. (35 P.S. § 623(d)). The Department also has the authority to promulgate regulations to implement and administer the act. (35 P.S. 625). These regulations exist primarily at 28 Pa. Code, Chapter 28. However, there is some overlap with these regulations in existing § 27.30 (related to reporting of cases of certain diseases in the newborn child), which the Department proposes to amend.

The Pennsylvania Cancer Control, Prevention and Research Act (35 P.S. § 5636), enacted in this Commonwealth in 1980, requires reporting of cancer cases to the Department. The United States Cancer Registries Amendment Act was thereafter enacted in 1992 to provide funding and technical assistance to

statewide cancer registries. *See* 42 U.S.C. §§ 280e—280e-5. The Federal law was amended in 2002 by the Benign Brain Tumor Cancer Registries Amendment Act (Pub. L. No. 107-260) to include requirements for reporting brain-related tumors. Finally, section 803 of the Health Care Facilities Act (35 P.S. § 448.803) provides the Department with the authority to promulgate regulations relating to the licensure of health care facilities and allows the Department to require certain actions relating to disease control and prevention to occur with in health care facilities.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The proposed regulations are not mandated by Federal law, court order or regulation. However, the Department has chosen, throughout the proposed regulations, to align with Federal guidance from the CDC.

With respect to state law, the Department has the general duty to protect the health of the people of this Commonwealth under § 2102(a) of the Administrative Code (71 P.S. § 532(a)) and is authorized by the Act to promulgate regulations related to this mandate. *See* 35 P.S. § 521.16(a). The Board is also required under § 2111(c.1) of the Administrative Code (35 P.S. § 5471(c.1)) to make, and revise from time to time, a list of communicable diseases against which children shall be required to be immunized as a condition of attendance at any public, private, or parochial school, in this Commonwealth.

With respect to state court decisions, in *Corman v. Acting Secretary of Pennsylvania Department of Health*, 266 A.3d 452 (Pa. 2021), the Pennsylvania Supreme Court directly addressed existing § 27.60(a) (relating to disease control measures) while deciding whether the Department had authority to issue a school-wide masking mandate during the COVID-19 pandemic. The Court in *Corman* noted that the broad powers given to the Department to enforce disease control measures were restricted by regulation, and pursuant to the current language of § 27.60(a) "surveillance" is the only reason by which the Department can enact a disease control measure like school-wide masking. *See* 35 P.S. § 521.5. Ultimately the Court held that the Department lacked the power to issue the masking mandate, but notably pointed out that "[o]f course, the Department has the power to promulgate a different regulation, or to amend this one, to. . . strip the 'any other disease control measure' catch-all of its limiting language." *Id*. at 484. The foregoing decision influenced the Department's proposed amendments to § 27.60(a), which propose to add "prevention, containment or mitigation" as justifications for the implementation of all disease control measures available to the Department under the Disease Prevention and Control Law.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The Department's regulations addressing communicable and noncommunicable diseases were first promulgated in 1959. The regulations were last significantly updated in 2001, which included updates to the list of reportable diseases, infections and conditions. The regulations were updated again in 2002 to add HIV to the list of reportable diseases, infections and conditions and again in 2020, to require reporting of all CD4 T-lymphocyte cell counts relating to HIV infection as well as viral load results and genotyping results. Comprehensive amendments to the regulations are needed to expand the list of reportable diseases, infections and conditions, to address changing standards and recommendations from experts, such as the CDC and the AAP, and to ensure the overall public health and safety by reducing the risk and spread of diseases, infections and conditions.

Over 400,000 health care practitioners, over 6,000 health care facilities, and 9,589 clinical laboratories will benefit from proposed amendments to reflect current terminology and enhance readability, such as the proposed alphabetical reporting charts in § 27.21a and 27.22. All 500 school districts, more than 160 brick-and-mortar charter schools, 14 cyber charter schools, approximately 396 colleges and universities, and 6,378 childcare group settings, and students and employees in those settings, will also benefit from similar proposed amendments to § 27.71a (relating to exclusion and readmission requirements for specific diseases, infections and conditions of food handlers, health care practitioners, schools, colleges and universities, child care group settings and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting). Children and staff in these settings will also benefit from amendments to readmission and exclusion requirements in proposed § 27.71a, to align with current recommendations from the AAP, which will ensure their health and safety by reducing the risk of exposure and becoming ill from certain diseases, conditions and infections.

The approximately 3,200 veterinarians will benefit from the Department's proposed amendments in § 27.24a and 27.35 which will eliminate double reporting to the Department and to the Pennsylvania Department of Agriculture. The general public, consisting of approximately 13 million individuals in this Commonwealth, will also benefit from the proposed amendments to expand the list of reportable diseases, infections and conditions, and from amendments to clarify existing requirements, such as the disease control measures that the Department may take under § 27.60. These proposed amendments will protect public health by ensuring that the Department may act appropriately and quickly when needed, which will result in benefits such as preventing the spread of a disease, condition or infection.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The Department has chosen throughout the proposed regulations to align with Federal guidance, such as the CDC's National Notifiable Diseases Surveillance System (NNDSS) for disease reporting requirements *See* CDC. (2025). 2025 National Notifiable Conditions. Retrieved from https://ndc.services.cdc.gov/search-results-year/. The Department elected to follow the American Academy of Pediatrics' (AAP) Recommended Child and Adolescent Immunization Schedule instead of the Advisory Committee on Immunization Practice's (ACIP) Child and Adolescent Immunization Schedule for child care group setting immunization requirements. *See* AAP. (2026). Recommended Child and Adolescent Immunization Schedule. Retrieved from https://downloads.aap.org/AAP/PDF/AAP-Immunization-Schedule.pdf; CDC. (2025). Child and Adolescent Immunization Schedule by Age. Retrieved from https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html. The Department proposes these amendments to align with evidence-based recommendations made by the nation's leading medical associations, in accordance with Executive Order 2025-02 – Protecting Pennsylvanians' Health and Freedom by Ensuring Access to Safe and Effective Vaccines. *See* Executive Order Commonwealth of Pennsylvania Governor's Office. (October 1, 2025). Executive Order 2025-02 – Protecting Pennsylvanians' Health and Freedom by Ensuring Access to safe and Effective Vaccines. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/oa/documents/policies/eo/2025-02.pdf.

Proposed § 27.22a (relating to reporting select agents or toxins) will require Pennsylvania laboratories to report a detected release, exposure, loss or theft of a select agent or toxin to the Department. The CDC and the Animal & Plant Inspection Service are primarily responsible for tracking select agents and toxins, and require immediate reporting via telephone, email, or facsimile of an incident. *See* 42 CFR 73.19. The Department proposes to expand this mandatory reporting to include the Department, for the purposes of an effective local

response to find, contain and otherwise protect those at risk of exposure, or treat individuals who have already been exposed.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

The Department reviewed regulations for the states surrounding Pennsylvania (Delaware, Maryland, New York, New Jersey, Ohio, Virginia and West Virginia).

Pennsylvania's ability to compete will not be affected by proposed § 27.4a (relating to reporting hospital emergency department visit data for syndromic surveillance), which will require hospitals to report emergency department visit data elements to the Department within 24 hours of a patient's presentation to the hospital's emergency department. Currently, Pennsylvania relies on voluntary reporting of this information, akin to New York, New Jersey, Ohio and Maryland. *See* New York State Department of Health. (2024). Electronic Syndromic Surveillance System (ESSS). Retrieved from https://www.health.ny.gov/professionals/reportable_diseases/esss/; New Jersey Department of Health. (2023). Syndromic Surveillance. Retrieved from https://www.nj.gov/health/meaningfuluse/syndromic-surveillance/; Ohio Department of Health. (2025) Syndromic Surveillance. Retrieved from https://odh.ohio.gov/know-our-programs/syndromic-surveillance/syndromic-surveillance; Maryland Department of Health Office of Preparedness and Response. (2025). Programs: Biosurveillance. Retrieved from https://health.maryland.gov/preparedness/Pages/programs_bio.aspx. The proposed amendments will align Pennsylvania with Delaware and West Virginia's communicable disease regulations, which allow for the Delaware Department of Health and Social Services and the West Virginia Department of Health and Human Services to mandate statewide emergency department syndromic surveillance reporting system. *See* 16 Del. Admin. Code § 4202-2.6; W. Va. Code R. § 64-7-12. The Department's proposed amendments will guarantee that the Department does not lose access to this vital public health data in the future.

Pennsylvania's ability to compete may be affected by proposed amendments to § 27.21a (relating to reporting of cases by health care practitioners and health care facilities), which will expand the list of diseases, infections and conditions that health care practitioners and health care facilities are required to report to the Department from 52 to 125. The Department's proposed amendments create a more comprehensive list of reportable diseases than that of Maryland, New York, New Jersey, Ohio and West Virginia. *See* COMAR 10.06.01.03; 10 NYCRR §§ 2.1, 2.10; N.J.A.C. § 8:57-1.5; OAC 3701-3-02; W. Va. Code R. § 64-7-3. Delaware's communicable disease regulations contain a similar reportable diseases list for health care provider reporting to the one proposed by the Department. *See* 16 Del. Admin. Code § 4202, app 1. These proposed amendments create consistency between Pennsylvania's list of reportable diseases and that of the CDC's NNDSS. Aligning with national standards for disease reporting will enhance Pennsylvania's ability to compete with its surrounding states.

Pennsylvania's ability to compete may be affected by proposed amendments to § 27.22 (relating to reporting of cases by clinical laboratories), which will expand the list of diseases, infections and conditions that a clinical laboratory has to report to the Department from 63 to 116. The proposed amendments create a more comprehensive list than those of Maryland, New Jersey and West Virginia. *See* COMAR 10.06.01.03(c); N.J.A.C. § 8:57-17; W. Va. Code R. § 64-7-3. Delaware's communicable disease regulations contain a similar list for laboratory reporting to the one proposed by the Department. *See* Del Admin Code §4202, app. 1. These proposed amendments create consistency between Pennsylvania's list of reportable diseases and that of the CDC's NNDSS. Aligning with national standards for laboratory reporting will enhance Pennsylvania's ability to compete with its surrounding states.

Pennsylvania's ability to compete may be affected by proposed § 27.22a (relating to reporting of select agents or toxins), which proposes a new requirement in these regulations that any laboratory that possesses, uses or transfers select agents or toxins to report a detected release, exposure, loss or theft of select agent or toxin to the Department's Bureau of Laboratories (BOL). This proposed addition aligns with national standards for tracking and response to incidents involving select agents as set by the CDC. The proposed language is more comprehensive than the regulations of other states surrounding Pennsylvania, except Virginia, which typically only address select agents and toxins by way of mandating physician or laboratory reporting of an individual's exposure or potential exposure. *See*, *e.g.,* COMAR 10.06.01.03(c)(3-1). Virginia recently updated its regulations to similarly align with national standards. *See* 12VAC5-90-280. The Department's ability to protect the public from the serious threat of incidents involving select agents will be greatly enhanced by an effective local response, and place Pennsylvania ahead of surrounding states in preparation for such events.

Pennsylvania's ability to compete will not be affected by proposed amendments to § 27.30 (relating to reporting cases of certain diseases in the newborn child), which adds a new requirement that cases of Neonatal Abstinence Syndrome (NAS) must be reported to the Department's Division of Newborn Screening and Genetics, Bureau of Family Health. Pennsylvania does currently receive this information from hospitals and birthing centers but relies on voluntary reporting. New Jersey and Maryland do not collect this information. West Virginia, New York and Delaware only require reporting for fetal alcohol syndrome~~,~~. *See* W. Va. Code R. § 64-81-4; 10 NYCRR § 22.3; 16 Del. Admin. Code § 4101 Appendix A. The Department's proposed amendments will guarantee that the Department does not lose access to this vital public health data in the future.

Pennsylvania's ability to compete will not be affected by proposed § 27.33a (relating to reporting treatment for sexually transmitted diseases and tuberculosis), which mandates health care provider and health care facility reporting of treatment for six sexually transmitted diseases and tuberculosis. This proposed section is more comprehensive than Maryland's relevant provisions, which only require reporting of treatment when a provider is treating syphilis. *See* COMAR 10.06.01.17 – 18. In Delaware, provider reporting of the treatment of sexually transmitted diseases shall be done within 24 hours, and within 4 hours for tuberculosis. *See* Del. Admin. Code § 4202-7.3.1.1. Ohio requires reporting the occurrence of cases under a healthcare provider's care or treatment by the end of the next business day but does not specify including specifics of the treatment. *See* Ohio Admin Code 3701-3-03, 3701-03-05.

Pennsylvania's ability to compete may be affected by proposed § 27.36 (relating to reporting immunization delivery), which will require health care practitioners, health care facilities or other individuals authorized by law to administer vaccines to report immunization administration to the Department's designated immunization information system, unless a patient has declined in writing. This proposed addition creates comparable requirements to New Jersey and Delaware, except that Delaware does not allow a patient to decline in writing. *See* N.J.A.C. 8:57-3.1 to app J; 16 Del. Admin. Code 4202-7.1.14. Maryland's communicable disease

regulations provide for the administration of its state immunization information system, but health care provider reporting to this system is voluntary, which is reflective of Pennsylvania's current requirements. *See* COMAR 10.06.03.01-09. West Virginia requires health care providers to report vaccine administration data for minors, while relying on voluntary reporting for adult individuals. *See* W. Va. Code R. § 64-7-6. Ohio, New York and Virginia do not have any requirements for reporting holistic vaccine administration data to a state immunization information system. Mandating reporting of vaccine administration will increase participation in Pennsylvania's immunization information system, improving its effectiveness as a public health tool and thereby aiding the Department's efforts to reduce vaccine-preventable disease, as well as providing Pennsylvania residents with a reliable source of immunization records for their own use, in the event that they do not have them.

Pennsylvania's ability to compete may be affected by proposed § 27.37 (relating to reporting birth defects and congenital anomalies), which will require a health care practitioner or health care facility to report certain types of birth defects and congenital anomalies through the Department's birth defects registry. Currently, Pennsylvania is the only state in its region that does not have a birth defect registry. *See, e.g.,* N.J.A.C. 8:20; W. Va. Code R. § 64-7-4; 10 NYCRR § 22.3. After an analysis of various state regulations, the Department created language comparable to that of Florida, due to its use of general types of birth defects as opposed to specific diagnostic codes which make the proposed language more adaptable. *See* Fla. Admin. Code Ann. R. 64D-3.035. This proposed section aims to make Pennsylvania competitive with the other states in its region with regards to identifying and preventing potential causes of birth defects.

Pennsylvania's ability to compete will not be affected by proposed amendments to § 27.60 (relating to disease control measures), which adds the words "prevention, containment or mitigation" to the list of purposes for which the Department can use disease control measures. This proposed amendment aligns Pennsylvania's disease control measure provisions with those of its neighboring states, such as New York, New Jersey and West Virginia. *See* 10 NYCRR § 2.13 (allowing for disease control measures to be enacted "whenever appropriate"); N.J.A.C. 8:57-1.11 (isolation and quarantine measures may be used as "medically and epidemiologically necessary to prevent or control the spread of the disease"); W. Va. Code R. § 64-7-21 (allowing for isolation and quarantine measures to prevent and control the spread of disease).

Pennsylvania's ability to compete may be affected by proposed § 27.60c (relating to contract tracing and partner services in schools), which requires schools to allow Departmental access to students, unobstructed and in private, for the purpose of contract tracing or partner services. None of the states surrounding Pennsylvania address partner services or contact tracing within their communicable disease regulations. Enabling Department personnel to utilize these important public health strategies to prevent the spread of disease in schools will place Pennsylvania ahead of other states in the region.

Pennsylvania's ability to compete may be affected by proposed amendments to § 27.71a, which expands the number of, and requirements for, the diseases, infections and conditions that warrant exclusion in the relevant settings. These proposed amendments create a list of cases excluded from handling food similar to that of New York, although New York does not have exclusion requirements for health care practitioners, schools or child care group settings. *See* 10 NYCRR § 2.50. New Jersey broadly excludes food handlers who have any reportable communicable disease, but likewise does not cover exclusion requirements for health care practitioners, schools or child care group settings. *See* N.J.A.C. 8:57-1.13. West Virginia allows for the exclusion of students or educators from school settings when suffering from any of the communicable diseases listed in its regulations but does not address food handlers. *See* W. Va. Code R. § 64-7-22. Maryland's relevant list is not as extensive as the one proposed by the Department but does generally cover the same persons. *See* COMAR 10.06.01.08-.21. The Department's more comprehensive proposed list of diseases,

conditions and infections prompting exclusion and case requirements for readmission will place Pennsylvania ahead of other states and enhance Pennsylvania's ability to compete.

Pennsylvania's ability to compete may be affected by proposed amendments to § 27.72 (relating to exclusions of children, students, staff and other persons having direct contact with children and students, for showing symptoms), which expand the list of symptoms justifying exclusion from school settings. The Department's proposed amendments create consistency between Pennsylvania's list of symptoms allowing exclusion and updated guidance from the American Academy of Pediatrics, maintaining Pennsylvania's competitive edge in childhood communicable disease prevention. *See* AAP. (2021). *Red Book: 2021 Report of the Committee on Infectious Disease, 32nd ed.*; AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.* None of the states surrounding Pennsylvania have similar provisions in regulations.

Pennsylvania's ability to compete may be affected by proposed amendments to § 27.77 (relating to immunization requirements for children in child care group settings), which lists specific diseases that children attending child care group settings must be immunized from. This proposed amendment creates a list of diseases comparable to that of New Jersey. *See* N.J.A.C. 8:57-4.1 to 4.24. Other surrounding states, such as New York, Ohio and West Virginia do not have requirements related to required immunizations for children attending child care group settings in their communicable disease regulations. The proposed amendments reflect recommendations from the AAP's Recommended Child and Adolescent Immunization Schedule, and by adhering to this national standard, Pennsylvania will remain ahead of many other states in its region with regards to childhood vaccinations in child care settings.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The Department's proposed expansion of the reportable diseases listed in § 27.21a will impact this Commonwealth's Department of Human Services' (DHS) regulations at 55 Pa. Code §§ 3270.136, 3280.136 and 3290.136, which direct facility persons of child day care centers, group child day care homes and family child day care homes to report any instance of a reportable communicable disease to the Department of Health. The proposed amendments' increased number of reportable diseases could require facility persons to contact DHS more frequently and may result in an increase in the number of staff and children being excluded from care, exacerbating operational challenges, such as staffing shortages, for child care facilities.

DHS regulations at 55 Pa. Code §§ 2380.111, 2380.113, 2380.114, 2600.16, 2800.16, 3800.16, 6400.152 and 6500.126 reference § 27.2. Although the Department does not propose substantive amendments to § 27.2, it cross-references the reportable diseases, infections and conditions of Subchapter B that the Department does propose to significantly increase in number. Therefore, each of the DHS regulations listed above will be impacted. For example, the proposed amendments will likely increase the amount of time that physicians working for family living homes must spend on writing specific instructions for individuals or their family members who have a communicable disease pursuant to 55 Pa. Code § 6500.126.

DHS regulations at 55 Pa. Code §§ 3270.137, 3280.137 and 3290.137, which mandate operators of child day care centers, group child day care homes and family child day care homes to exclude children based on the symptoms listed in § 27.72, will be affected by the Department's proposed additions to that section via more frequent exclusion of children from those settings.

DHS regulations at 55 Pa. Code §§ 3270.153, 3280.153 and 3290.153, which address employee exclusion from child day care centers, group child day care homes and family child day care homes for having symptoms, are dependent upon "the diseases and conditions specified in Chapter 27." These provisions may be impacted by

proposed changes to § 27.71a. Since the Department's proposed amendments to this section increase the number of diseases listed, this could result in more frequent absences for facility persons from the aforementioned child care settings.

The Department proposes to amend § 27.77 by changing the word "vaccinate" to "immunize," reflecting that a child may attend a child care group setting by either providing proof of vaccination, inoculation or medical records demonstrating natural immunity. The Department also proposes to replace annual immunization status reporting with a requirement that child care settings provide such information to the Department upon request. These proposed changes will affect DHS regulations at 55 Pa. Code §§ 3270.131, 3280.131 and 3290.131, which require child day care centers, group child day care homes and family child day care homes to implement policies related to dismissal based on noncompliance with § 27.7 generally, and to abide by the annual immunization reporting requirement at §27.77(a)(4). The proposed amendments' removal of the annual reporting requirement will reduce the administrative burden of child care settings regulated under DHS. However, these same child care settings may be required to update policies related to a child's dismissal if they do not account for a child's natural immunity from the diseases listed in §27.77(b)(2).

The proposed amendments to § 27.77 also impacts the Department of Education's regulations at 22 Pa. Code § 405.49, which states that child care centers and group child care homes providing PA Pre-K Counts services must meet the immunization requirements of § 27.77. The proposed amendments may require these child care centers and group child care homes to change policies and procedures regarding attendee immunization status to include inoculation and natural immunity from the listed diseases. Additionally, removal of the annual reporting requirement will reduce these providers' administrative burden.

Department of Aging regulations at 6 Pa. Code § 11.3 defines "unusual incident" to include an "[o]utbreak of a communicable disease, as defined in 28 Pa. Code § 27.2 (relating to specific identified reportable diseases, infections and conditions) to the extent that confidentiality laws permit reporting." Department of Aging regulations require older adult living centers to report unusual incidents in 6 Pa. Code § 11.16. Although the Department does not propose substantive amendments to § 27.2, it cross-references the reportable diseases, infections and conditions of Subchapter B that the Department does propose to significantly increase in number. The proposed amendments may require older adult living centers to report additional unusual incidents to the Department of Aging.

The Department reached out to these agencies to discuss and present the proposed amendments in the summer of 2024. The Department also shared a copy of the proposed amendments with these agencies in December 2025.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Department engaged with relevant stakeholders, potentially impacted agencies and local health departments in the spring and summer of 2024.

Representatives from the following organizations participated in presentations and discussions held by the Department, in the summer of 2024, on proposed amendments to the regulations: the Children's Hospital of Philadelphia, Pennsylvania Medical Society, the Hospital and Healthsystem Association of Pennsylvania, Pennsylvania Association of Community Health Centers, Philadelphia Department of Public Health, Erie

County Department of Health, City of Philadelphia, PA Thrive Partnership Erie, LeadingAge PA, Pennsylvania State System of Higher Education, PA Association of School Administrators, Lehigh Valley Health Network, Montgomery County Department of Human Services, Doylestown Health, Doylestown Hospital, Main Line Health, Chester County Hospital, Hospital of the University of Pennsylvania, Jefferson Einstein Hospital, Pennsylvania Hospital, Patient Safety Authority, Jefferson Health System, and Temple Health Chestnut Hill Hospital.

The Department met with local health departments on May 10, 2024, to discuss and present the proposed amendments to the regulations. The following local health departments participated in that discussion: Philadelphia Department of Public Health, Allegheny County Health Department, York City Health Bureau, Bucks County Department of Health, Delaware County Health Department, Montgomery County Health Department, Chester County Health Department, Bethlehem Health Bureau, Wilkes-Barre City Health Department, Allentown Bureau of Health, Erie County Department of Health.

The Department reached out to sister agencies to discuss and present the proposed amendments to the regulations. On June 12, 2024, the Department met with the Pennsylvania Department of Education and the Pennsylvania Department of Human Services. On June 13, 2024, the Department met with the Pennsylvania Department of Environmental Protection, Pennsylvania Department of Drug and Alcohol Programs, Pennsylvania State Police, Pennsylvania Department of State, Pennsylvania Department of Conservation and Natural Resources, Pennsylvania Emergency Management Agency, and Pennsylvania Department of Agriculture. The Department also shared a final draft of the proposed amendments with these agencies and the Pennsylvania Department of Aging in December 2025.

The proposed amendments incorporate feedback received from relevant stakeholders, potentially impacted agencies and local health departments.
Finally, the Department met with the Board for review and approval of the proposed amendments to the regulations in accordance with section 16(a) of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.16(a)). The Board approved the proposed amendments on July 17, 2025.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Health Care Practitioners and Health Care Facilities

Over 400,000 health care practitioners and over 6,000 health care facilities in this Commonwealth will be affected by the proposed rulemaking, as they will have to comply with the proposed amendments. *See* U.S. Bureau of Labor Statistics. (2024). Occupational Employment and Wage Statistics: Pennsylvania. Retrieved from https://data.bls.gov/oes/#/area/4200000; and Pennsylvania Department of Health. (2025). Quality Assurance Programs: Report for Fiscal Year 2022-2023. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/facilities-and-licensing/General%20Assembly%20Report%202022-2023.pdf. These practitioners and facilities will benefit from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.21a (relating to reporting of cases by health care practitioners and health care facilities), which will make it easier for these practitioners and facilities to comply with the regulations, which may result in cost savings through efficiencies.

All health care practitioners and health care facilities will be affected by proposed amendments to § 27.21a, which will increase the number of diseases, infections and conditions that practitioners and facilities will have to report to the Department's electronic disease surveillance system (PA-NEDSS). All practitioners and facilities are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. In addition, for those that manually report, effects will vary based on factors such as the number of patients seen at a location, the number of reportable diseases diagnosed at each location, and the type of individual hired to perform this function. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report to estimate the effect to these practitioners and facilities.

All health care practitioners and health care facilities will be affected by the proposed addition of § 27.33a (relating to reporting of treatment for sexually transmitted diseases and tuberculosis), which will require reporting treatment provided to all suspected or confirmed cases of tuberculosis and certain sexually transmitted diseases. Practitioners and facilities will be required to report to the Department's already-existing electronic disease surveillance system (PA-NEDSS) or to the local health department. Practitioners and facilities that electronically report will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. In addition, for those that manually report, effects will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report to estimate the effect on these practitioners and facilities.

Some health care practitioners and health care facilities, and individuals authorized by law to administer immunizations, will be affected by the proposed addition of § 27.36 (relating to reporting immunization delivery), which will require these practitioners, facilities and individuals to report each immunization administration in all counties of this Commonwealth, except Philadelphia County, to the Department's designated immunization information system. Philadelphia County is excluded from this requirement as they have their own reporting system already in place. The Department estimates that approximately 21,000 health care practitioners, facilities and individuals will need to comply with this new requirement. Out of this number, 16,250 are already voluntarily reporting to the Department's immunization electronic registry system (PIERS). The 4,750 not currently reporting will need to establish a process for reporting to PIERS, either electronically or manually, which may require additional staff or IT support. The effects on these practitioners, facilities and individuals will also vary depending on factors such as the number of immunizations that are being reported and who is hired to perform this function. The Department does not currently have sufficient data to estimate the effects on these 4,750 practitioners, facilities and individuals.

All health care practitioners and health care facilities will be affected by the proposed addition of § 27.37 (relating to reporting birth defects and congenital anomalies) which will require practitioners and facilities to report certain birth defects and congenital anomalies to the Department. Specifically, practitioners and facilities will need to establish a system for reporting birth defects to the Department's newly created electronic birth defects registry. This may involve creating an electronic system for automated reporting or allocating staff to manually submit data to the Department's birth defects registry, the cost of which will vary depending on factors such as the number of patients with reportable birth defects and the type of individual hired to perform this function. The Department does not have sufficient data to accurately estimate the effect of this proposed amendment.

All health care practitioners and health care facilities will be affected by new proposed § 27.71a, which will update the exclusion and readmission requirements for health care practitioners. The Department does not propose to increase the total number of entries which require exclusion; however, the proposed amendments do remove a broad symptom of disease from the exclusion requirements and replace it with a specific disease. Health care practitioners may experience fewer exclusions because of this change. Health care facilities may lose less staff time to exclusions under this new proposed section. The Department cannot accurately estimate the difference in the number of exclusions this proposed change will cause.

Health care practitioners within the scope of their practice who attend, treat or examine pregnant individuals may be affected by the proposed addition of §§ 27.99a and 27.99b (relating to prenatal examination for hepatitis C and prenatal examination for HIV), which will require them to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. The factors in determining the effects on these practitioners will vary depending on each practitioner's practice, such as additional paperwork to order the blood draw, additional time from staff drawing blood or costs in submitting the sample to a laboratory for testing. Costs for drawing the blood sample may be offset, in some cases, by the pregnant individual's insurance plan or the pregnant individual paying out-of-pocket for the test. Administrative costs, such as paperwork, may be absorbed by the practitioner as a cost of business. The Department does not have sufficient data to accurately estimate the effect of this proposed amendment.

Laboratories

All 9,589 clinical laboratories in this Commonwealth will be affected by the proposed amendments as they will need to comply with them. *See* Pennsylvania Department of Health. (2025). Laboratory Improvement. Retrieved from https://www.pa.gov/agencies/health/healthcare-and-public-health-professionals/laboratories/laboratory-improvement.html. These laboratories will benefit from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.22 (relating to reporting of cases by clinical laboratories), which will make it easier for them to comply with the regulations, which may result in efficiencies.

All clinical laboratories will be affected by proposed amendments to § 27.22, which will increase the number of diseases, infections and conditions that they will have to report to the Department. All clinical laboratories are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Clinical laboratories that manually report will need to allocate additional resources, including staff time, to submit data to the Department. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. The Department does not have sufficient data to determine the number of clinical laboratories that electronically and manually report to estimate the effects on these practitioners and facilities.

Clinical, research or commercial laboratories, in this Commonwealth, that are registered with the Federal Select Agent Program (FSAP) to possess, use or transfer select agents or toxins will be affected by the addition of proposed § 27.22a (relating to reporting of select agents or toxins), which will require these laboratories to report a detected release, exposure, loss or theft of a select agent or toxin to BOL. Currently, there are six laboratories to whom this requirement will apply. These laboratories will be required to add the Department to any existing process or system they currently have in place for complying with already-existing requirements by FSAP.

Schools, Colleges, Universities and Childcare Group Settings

All 500 school districts, which range in size from approximately 200 students to more than 140,000 students, and more than 160 brick-and-mortar charter schools and 14 cyber charter schools, which educate approximately 135,000 students, and the approximately 199,000 individuals employed by public and private schools, will be affected to the extent they are required to comply with the proposed amendments. *See* Pennsylvania Department of Education. (2025). Types of Schools. Retrieved from https://www.pa.gov/agencies/education/resources/types-of-schools.html; National Center for Education Statistics. (2021). Pennsylvania. Retrieved from https://nces.ed.gov/programs/digest-dashboard/state/pennsylvania. Approximately 400 colleges and universities in this Commonwealth, and 633,991 students and 161,146 employees in those settings, will be affected to the extent that they are required to comply with the proposed amendments. Pennsylvania Department of Education. (2025). Types of Schools. Retrieved from https://www.pa.gov/agencies/education/resources/types-of-schools.html; Education Data Initiative. (2025). College Enrollment & Student Demographic Statistics. Retrieved from https://educationdata.org/college-enrollment-statistics. Additionally, all 6,378 childcare group settings in this Commonwealth and their 96,197 employees will be affected by the proposed amendments to the extent that they will need to comply with them. Pennsylvania Office of Child Development and Early Learning. (2023). Commonwealth of Pennsylvania 2022 Market Rate Survey Report. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/services/children/documents/child-care-early-learning/2022_MRS_Summary_Report_FINAL.pdf; Commonwealth of Pennsylvania Open Data Portal. (2025). PA Child Care Workforce Care Levels Served by STAR Level Current Human Services. Retrieved from https://data.pa.gov/K-12-Education/PA-Child-Care-Workforce-Care-Levels-Served-by-STAR/kwmw-yk2h/data_preview.

Schools, colleges, universities and childcare group settings will benefit from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for exclusion and readmission requirements in proposed § 27.71a, which will make it easier to comply with the regulations and may result in efficiencies.

All schools, colleges, universities and childcare group settings will be affected by proposed amendments to § 27.71a, which will add exclusion and readmission requirements for 18 diseases, infections and conditions to the existing list. The proposed amendments, including the addition of exclusion and readmission requirements for 18 new diseases, infections and conditions, align with current recommendations from the American Academy of Pediatrics (AAP) and will ensure the health and safety of students and staff attending these entities. However, these entities may also be negatively affected by an increase in staff and student absences from this expansion, necessitating the need, for example, to employ substitute teachers. Because this cost will vary based on the number of illnesses and time missed, the Department is not able to estimate the specific effects of this proposed amendment.

All schools will be affected by the proposed addition of § 27.60c (relating to contact tracing and partner services in schools), which will require a school to provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises or attending a school function. Compliance with this requirement may result in a time disruption to schools, which will vary based on the disease, infection or condition being investigated. Therefore, the Department is not able to estimate the specific effects of the proposed amendment.

Veterinarians

Approximately 3,200 veterinarians in this Commonwealth will be affected by the proposed amendments, to the extent that they will be required to comply with them. *See* U.S. Bureau of Labor Statistics. (2024). Occupational Employment and Wage Statistics: Pennsylvania. Retrieved from https://data.bls.gov/oes/#/area/4200000. All veterinarians will be affected by the proposed addition of specific diseases, infections and conditions in § 27.24a (relating to reporting of cases by veterinarians). The Department consulted with the Pennsylvania Department of Agriculture, and is proposing to limit the reporting of diseases, infections and conditions, which may be transmitted from animals to humans, to the Department that are already not being reported to the Department of Agriculture to prevent double reporting. This may result in cost savings through efficiencies. Factors that would determine such savings are variable and dependent on many factors. Therefore, the Department is not able to estimate the specific effects of the proposed amendment.

General Public

The general public, consisting of approximately 13 million individuals in this Commonwealth, will be affected by the proposed amendments, to the extent that they are required to comply with them. See U.S. Census Bureau. (2024). Quick Facts: Pennsylvania. Retrieved from https://www.census.gov/quickfacts/fact/table/PA/PST045223. They will also be positively affected by proposed amendments to expand various reporting requirements by health care practitioners, health care facilities and laboratories, as this information will be utilized by the Department to conduct investigations and take appropriate measures to protect public health. Other proposed amendments clarifying existing requirements, such as the disease control measures that the Department may take under § 27.60 (relating to disease control measures), will also protect the public health by ensuring that the Department may act appropriately and quickly when needed, which will result in benefits such as preventing the spread of a disease, condition or infection. This could result in cost savings to the public, such as a reduction in health care expenses and less missed time from work. Because circumstances vary, the Department is not able to specifically estimate the effects of these proposed amendments.

Additional proposed requirements relating to exclusion and readmission of students, children, staff, food handlers and health care practitioners may result in individuals missing time from work or school, but will prevent the spread of contagious diseases, infections and conditions in settings such as schools, colleges, universities, and child care group settings. However, the Department made an effort, where appropriate, to remove the need for health care provider verification for readmission, which will alleviate the time and monetary burden for parents, guardians, and other individuals potentially impacted by the proposed exclusion requirements.

Pregnant individuals will be affected by the proposed addition of §§ 27.99a and 27.99b (relating to prenatal examination for hepatitis C and prenatal examination for HIV), which will require health care practitioners acting within the scope of their practice who attend, treat or examine pregnant individuals to obtain and submit a sample of blood to be tested for hepatitis C and HIV. These additional tests may result in a cost to patients if not covered by their health insurance plan, as detailed further in question 19, but will benefit these individuals and their unborn fetuses by ensuring early, preventative treatment is provided to improve the health outcome of both the pregnant individual and the child.

Local health departments

All 11 county and municipal health departments in Pennsylvania, collectively referred to as local health departments, will be affected by proposed amendments to §§ 27.32d and 27.32e (relating to department

authority to require complete reporting and record audits), which will allow local health departments to have access to, review and conduct audits of HIV-related patient records. This proposed amendment will allow for local health department disease investigation personnel to conduct all disease investigations within their jurisdiction, where they are the primary investigator, potentially minimally increasing the workload for those personnel. Local health departments will be affected by proposed amendments to § 27.42a (relating to reporting by local health departments of completed case investigations), which will extend the deadline to submit a case investigation report from each case investigation that results in a confirmed reportable disease. The proposed 2-day extension will give local health departments more time to complete reports. Local health departments will be affected by proposed amendments to § 27.67 (relating to movement of persons and animals subject to isolation or quarantine by action of a local health authority or the department), which will require local health departments to grant permission for the interstate transportation of a person or animal under isolation or quarantine if involved. This proposed amendment will ensure that local health departments are informed and involved in such cases of interstate transportation.

Department

The Department will also be affected by proposed amendments to § 27.22(l), which will require a clinical laboratory, if it suspects the presence of certain select agents or toxins, to submit specimens or cultures to BOL or another laboratory designated by BOL. There is no additional cost to the laboratory, but there would be a cost to BOL, who bears all of the associated costs for courier pick-up and transport of the suspected specimens, and for the testing, and for shipping presumptive positive specimens to the CDC for confirmatory testing. The Department is not able to estimate a specific cost, as this would depend on the number of specimens or cultures sent to BOL. However, courier costs vary by county location, currently ranging from $50 to $90 plus a fuel surcharge. BOL estimates an average cost of $75/specimen, which is typically delivered next day. During emergent events (*e.g.* H5 avian influenza), BOL requests express delivery (same day pickup and drop-off at $2.25/mile). In that scenario, a package from Erie County would cost over $900, for example.

The Department will also be affected by the proposed addition of § 27.37, which will require the Department to establish a birth defects registry and will result in a substantial cost to the Department that may be offset by funding from the CDC. A more specific analysis of this cost and potential savings is detailed in *Question 22*.

Small Business Analysis

Under section 3 of the Regulatory Review Act, 71 P.S. § 745.3, a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many health care practitioners, health care facilities, laboratories, schools and child care group settings are small businesses.

Based on these Federal standards, the Department determined that a physician's office is a small business if it has $16 million or less in annual receipts, and a dentist's office, chiropractor's office, podiatrist's office, and optometrist's office is a small business if it has $9 million or less in annual receipts, and offices of all other health care practitioners are considered a small business if they have $10 million or less in annual receipts. A veterinary office is a small business if it has $10 million or less in annual receipts. A clinical laboratory is a small business if it has $41.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of physician's offices, dentist's offices, chiropractor's offices, optometrist's offices,

other health care practitioners, veterinary offices, or clinical laboratories that would be classified as a small business under this definition.

Using the same Federal standards, the Department determined that a hospital is a small business if it has $47 million or less in annual receipts, a long-term care nursing facility is a small business if it has $34 million or less in annual receipts, home health care services are a small business if they have $19 million or less in annual receipts, and all other health care services are considered a small business if they have $20.5 million or less in annual receipts. The Department estimates that 26 hospitals and 624 long-term care nursing facilities, would be considered to be a small business under the Federal standards. *See* PHC4. (2025). Financial Analysis 2023, Volume One. Retrieved from https://www.phc4.org/wp-content/uploads/fin2023report_volumeone.pdf; Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data; and GuideStar. Retrieved from https://www.guidestar.org/. The Department does not have sufficient data to determine the number of home health or other health care facilities that would meet the criteria for a small business.

Using the same Federal standards, the Department determined that an elementary or secondary school is a small business if it has $20 million or less in annual receipts. Based on total revenue data from the Pennsylvania Department of Education for school districts in this Commonwealth, the Department estimates that approximately 39% (295 out of 754) of school districts would be classified as a small business under this definition. *See* Pennsylvania Department of Education. (2023). AFR Data: Summary-Level. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/education/documents/schools/grants-and-funding/school-finances/summary-of-afr-data/afr-data-summary-level/finances%20afr%20revenues%202022-2023.xlsx. A college or university is a small business if it has $34.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of colleges or universities that would be classified as a small business under this definition. The Department also determined, using the same Federal standards, that a child care group setting is a small business if it has $9.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of child care group settings that would be classified as a small business under this definition.

The Department did not establish different criteria for small businesses. The Department's responsibility to protect public health through the prevention and control of diseases, infections and conditions necessitates compliance by all health care practitioners, facilities, laboratories, schools, colleges, universities, child care group settings, food handlers, veterinarians, and the general public, regardless of whether these entities and individuals are considered small businesses.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

Over 400,000 health care practitioners and 6,000 health care facilities in this Commonwealth will be required to comply with the proposed amendments. *See* U.S. Bureau of Labor Statistics. (2024). Occupational Employment and Wage Statistics: Pennsylvania. Retrieved from https://data.bls.gov/oes/#/area/4200000; and Pennsylvania Department of Health. (2025). Quality Assurance Programs: Report for Fiscal Year 2022-2023. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/facilities-and-licensing/General%20Assembly%20Report%202022-2023.pdf.

All 500 school districts, which range in size from approximately 200 students to more than 140,000 students, and more than 160 brick-and-mortar charter schools and 14 cyber charter schools, which educate approximately 135,000 students, and the approximately 199,000 individuals employed by public and private schools, will be required to comply with the proposed amendments. *See* Pennsylvania Department of Education. (2025). Types of Schools. Retrieved from https://www.pa.gov/agencies/education/resources/types-of-schools.html; National Center for Education Statistics. (2021). Pennsylvania. Retrieved from https://nces.ed.gov/programs/digest-dashboard/state/pennsylvania.

Approximately 400 colleges and universities in this Commonwealth, and 633,991 students and 161,146 employees in those settings, will be required to comply with the proposed amendments. Pennsylvania Department of Education. (2025). Types of Schools. Retrieved from https://www.pa.gov/agencies/education/resources/types-of-schools.html; Education Data Initiative. (2025). College Enrollment & Student Demographic Statistics. Retrieved from https://educationdata.org/college-enrollment-statistics.

All 9,589 clinical laboratories, as well as six laboratories that are registered with the FSAP to possess, use or transfer select agents or toxins, in this Commonwealth, will be required to comply with the proposed amendments. *See* Pennsylvania Department of Health. (2025). Laboratory Improvement. Retrieved from https://www.pa.gov/agencies/health/healthcare-and-public-health-professionals/laboratories/laboratory-improvement.html.

All 6,378 child care group settings in this Commonwealth, and 96,197 individuals employed in those settings, will be required to comply with the proposed amendments. *See* Pennsylvania Office of Child Development and Early Learning. (2023). Commonwealth of Pennsylvania 2022 Market Rate Survey Report. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/services/children/documents/child-care-early-learning/2022_MRS_Summary_Report_FINAL.pdf; Commonwealth of Pennsylvania Open Data Portal. (2025). PA Child Care Workforce Care Levels Served by STAR Level Current Human Services. Retrieved from https://data.pa.gov/K-12-Education/PA-Child-Care-Workforce-Care-Levels-Served-by-STAR/kwmw-yk2h/data_preview.

Approximately 3,200 veterinarians in this Commonwealth will be required to comply with the proposed amendments. *See* U.S. Bureau of Labor Statistics. (2024). Occupational Employment and Wage Statistics: Pennsylvania. Retrieved from https://data.bls.gov/oes/#/area/4200000.

The general public, consisting of approximately 13 million individuals in this Commonwealth, will be required to comply with the proposed amendments. *See* U.S. Census Bureau. (2024). Quick Facts: Pennsylvania. Retrieved from https://www.census.gov/quickfacts/fact/table/PA/PST045223.

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(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

Health care practitioners and health care facilities

Over 400,000 health care practitioners and over 6,000 health care facilities in this Commonwealth will be impacted by the proposed rulemaking. These practitioners and facilities will be positively impacted by proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.21a (relating to reporting

of cases by health care practitioners and health care facilities), which will make it easier for these practitioners and facilities to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All health care practitioners and health care facilities will be financially impacted by proposed amendments to § 27.21a, which will increase the number of diseases, infections and conditions that practitioners and facilities will have to report to the Department's electronic disease surveillance system (PA-NEDSS). All practitioners and facilities are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients seen at a location, the number of reportable diseases diagnosed at each location, and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by the proposed addition of § 27.33a (relating to reporting of treatment for sexually transmitted diseases and tuberculosis), which will require reporting treatment provided to all suspected or confirmed cases of tuberculosis and certain sexually transmitted diseases. Practitioners and facilities will be required to report to the Department's already-existing electronic disease surveillance system or to the local health department. Practitioners and facilities that electronically report will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Some health care practitioners and health care facilities, and individuals authorized by law to administer immunizations, will be financially impacted by the proposed addition of § 27.36 (relating to reporting immunization delivery), which will require these practitioners, facilities and individuals to report each immunization administration in all counties of this Commonwealth, except Philadelphia County, to the Department's designated immunization information system. Philadelphia County is excluded from this requirement as they have their own reporting system already in place. The Department estimates that approximately 21,000 health care practitioners, facilities and individuals will need to comply with this new requirement. Out of this number, 16,250 are already voluntarily reporting to the Department's immunization electronic registry system (PIERS). The 4,750 not currently reporting will need to establish a process for reporting to PIERS, either electronically or manually, which may require additional staff or IT support and will vary depending on factors such as the number of immunizations that are being reported and who is hired to perform this function. The Department does not currently have sufficient data to estimate the financial impact to these 4,750 practitioners, facilities and individuals. For this reason, the Department is estimating no overall financial impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by the proposed addition of § 27.37 (relating to reporting birth defects and congenital anomalies) which will require practitioners and facilities to report certain birth defects and congenital anomalies to the Department. Specifically, practitioners and facilities will need to establish a system for reporting birth defects to the Department's newly created electronic birth defects registry. This may involve creating an electronic system for automated reporting or allocating staff to manually submit data to the Department's birth defects registry, the cost of which will vary depending on factors such as the number of patients with reportable birth defects and the type of individual hired to perform this function. The Department does not have sufficient data to estimate the cost of creating an electronic system or the amount of staff time needed for such reporting. For this reason, the Department is estimating no overall fiscal impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by new proposed § 27.71a, which will update the exclusion and readmission requirements for health care practitioners. The Department does not propose to increase the total number of entries which require exclusion; however, the proposed amendments do remove a broad symptom of disease from the exclusion requirements and replace it with a specific disease. Health care practitioners may experience fewer exclusions because of this change. Health care facilities may lose less staff time to exclusions under this new proposed section. The Department cannot accurately estimate the difference in the number of exclusions this proposed change will cause.

Health care practitioners within the scope of their practice who attend, treat or examine pregnant individuals may be financially impacted by the proposed addition of §§ 27.99a and 27.99b (relating to prenatal examination for hepatitis C and prenatal examination for HIV), which will require them to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. The factors in determining fiscal impact will vary depending on each practitioner's practice, such as additional paperwork to order the blood draw, additional time from staff drawing blood or costs in submitting the sample to a laboratory for testing. Costs for drawing the blood sample may be offset, in some cases, by the pregnant individual's insurance plan or the pregnant individual paying out-of-pocket for the test. Administrative costs, such as paperwork, may be absorbed by the practitioner as a cost of business. Due to these varying factors, the Department is not able to estimate a specific cost or savings impact.

Laboratories

All 9,589 clinical laboratories in this Commonwealth will be impacted by the proposed amendments. These laboratories will benefit from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.22 (relating to reporting of cases by clinical laboratories), which will make it easier for them to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All clinical laboratories will be financially impacted by proposed amendments to § 27.22(b) and (c), which will increase the number of diseases, infections and conditions, as well as the types of data, that they will have to report to the Department. All clinical laboratories are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Clinical laboratories that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of clinical laboratories that electronically and

manually report to estimate the financial impact to these practitioners and facilities. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Clinical, research or commercial laboratories, in this Commonwealth, that are registered with the Federal Select Agent Program (FSAP) to possess, use or transfer select agents or toxins will be impacted by the addition of proposed § 27.22a (relating to reporting of select agents or toxins), which will require these laboratories to report a detected release, exposure, loss or theft of a select agent or toxin to BOL. Currently, there are six laboratories to whom this requirement will apply and will require these laboratories to add the Department to any existing process or system they currently have in place for complying with already-existing requirements by FSAP. The Department does not have sufficient data to estimate the cost of this task but anticipates that any cost would be minimal. For this reason, the Department is estimating no overall fiscal impact for this requirement.

Schools, Colleges, Universities and Childcare Group Settings

All 500 school districts, which range in size from approximately 200 students to more than 140,000 students, and more than 160 brick-and-mortar charter schools and 14 cyber charter schools, which educate approximately 135,000 students, and the approximately 199,000 individuals employed by public and private schools, will be impacted by the proposed amendments. Approximately 400 colleges and universities in this Commonwealth, and 633,991 students and 161,146 employees in those settings, will be impacted by the proposed amendments. Additionally, all 6,378 childcare group settings in this Commonwealth and the 96,197 individuals employed in those settings will be impacted by the proposed amendments. Schools, colleges, universities and childcare group settings will be positively impacted from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for exclusion and readmission requirements in proposed § 27.71a, which will make it easier to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All schools, colleges, universities and childcare group settings may be financially impacted by proposed amendments to § 27.71a, which will add exclusion and readmission requirements for 18 diseases, infections and conditions to the existing list. The proposed amendments, including the addition of exclusion and readmission requirements for 18 new diseases, infections and conditions, align with current recommendations from the American Academy of Pediatrics (AAP) and will ensure the health and safety of students and staff attending these entities. However, these entities may also be financially impacted by an increase in staff and student absences from this expansion, necessitating the need, for example, substitute teachers. Because this cost will vary based on the number of illnesses and time missed, the Department is not able to estimate a specific cost. For that reason, the Department is estimating no overall fiscal impact for this requirement.

All schools may be impacted by the proposed addition of § 27.60c (relating to contact tracing and partner services in schools), which will require a school to provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises or attending a school function. Compliance with this requirement may result in a time disruption to schools, which will vary based on the disease, infection of condition being investigated. Because of the inability to estimate a specific cost, the Department is estimating no overall fiscal impact for this requirement.

Veterinarians

Approximately 3,200 veterinarians in this Commonwealth will be impacted by the proposed amendments. All veterinarians will be positively impacted by the proposed addition of specific diseases, infections and conditions in § 27.24a (relating to reporting of cases by veterinarians). The Department consulted with the Pennsylvania Department of Agriculture, and is proposing to limit the reporting of diseases, infections and conditions, which may be transmitted from animals to humans, to the Department that are already not being reported to the Department of Agriculture to prevent double reporting. This may result in a cost savings through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

General Public

The general public, consisting of approximately 13 million individuals in this Commonwealth, will be impacted by the proposed amendments. The public will be positively impacted by proposed amendments to expand various reporting requirements by health care practitioners, health care facilities and laboratories, as this information will be utilized by the Department to conduct investigations and take appropriate measures to protect public health. Other proposed amendments clarifying existing requirements, such as the disease control measures that the Department may take under § 27.60 (relating to disease control measures), will also protect the public health by ensuring that the Department may act appropriately and quickly when needed, which will result in benefits such as preventing the spread of a disease, condition or illness. This could result in cost savings to the public, such as a reduction in health care expenses and less missed time from work. Factors involved in calculating this cost savings will vary depending on the circumstances. For that reason, the Department is estimating no fiscal savings to the general public due to these amendments.

Additional proposed requirements relating to exclusion and readmission of students, children, staff, food handlers and health care practitioners may result in a financial impact due to individuals missing time from work or school, but will prevent the spread of contagious diseases, infections and conditions in settings such as schools, colleges, universities, and child care group settings. However, the Department made an effort, where appropriate, to remove the need for health care provider verification for readmission, which will alleviate the time and monetary burden for parents, guardians, and other individuals potentially impacted by the proposed exclusion requirements. Factors involved in calculating cost and savings related to time vary depending on the circumstances. Therefore, the Department is estimating no overall fiscal impact for these requirements.

All persons working as food handlers and their employers will be financially impacted by new proposed § 27.71a, which will update the exclusion and readmission requirements for food handlers. The Department does not propose to increase the total number of entries which require exclusion; however, the proposed amendments do remove a broad symptom of disease from the exclusion requirements and replace it with a specific disease. Food handlers may experience fewer exclusions because of this change. Entities that employ food handlers may lose less staff time to exclusions under this new proposed section. The Department cannot accurately estimate the difference in the number of exclusions this proposed change will cause.

Pregnant individuals will be impacted by the proposed addition of §§ 27.99a and 27.99b, which will require health care practitioners acting within the scope of their practice who attend, treat or examine pregnant individuals to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. These additional tests may result in a cost to patients if not covered by their health insurance plan, as detailed further in question 19, but will benefit these individuals and their unborn fetuses by ensuring early, preventative treatment is provided to improve the health outcome of both the pregnant individual and the child.

Local health departments

All 11 local health departments will be impacted by proposed amendments to §§ 27.32d and 27.32e, which will allow local health authorities to have access to, review and conduct audits of HIV-related patient records. This proposed amendment will allow for local health department disease investigation personnel to conduct all disease investigations within their jurisdiction, where they are the primary investigator, potentially minimally increasing the workload for those personnel. Local health departments will be impacted by proposed amendments to § 27.42a, which will extend the deadline to submit a case investigation report from each case investigation that results in a confirmed reportable disease. The proposed 2-day extension will give local health departments more time to complete reports. Local health departments will be impacted by proposed amendments to § 27.67 (relating to movement of persons and animals subject to isolation or quarantine by action of a local health authority or the department), which will require local health departments to grant permission for the interstate transportation of a person or animal under isolation or quarantine if involved. This proposed amendment will ensure that local health departments are informed and involved in such cases of interstate transportation.

Department

The Department will also be financially impacted by proposed amendments to § 27.22(l), which will require a clinical laboratory, if it suspects the presence of certain select agents or toxins, to submit specimens or cultures to BOL or another laboratory designated by BOL. There is no additional cost to the laboratory, but there would be a cost to BOL, who bears all of the associated costs for courier pick-up and transport of the suspected specimens, and for the testing, and for shipping presumptive positive specimens to the CDC for confirmatory testing. The Department is not able to estimate a specific cost, as this would depend on the number of specimens or cultures sent to BOL. However, courier costs vary by county location, currently ranging from $50 to $90 plus a fuel surcharge. BOL estimates an average cost of $75/specimen, which is typically delivered next day. During emergent events (*e.g.* H5 avian influenza), BOL requests express delivery (same day pickup and drop-off at $2.25/mile). In that scenario, a package from Erie County would cost over $900, for example.

The Department will be financially impacted by the proposed addition of § 27.37, which will require the Department to establish a birth defects registry and will result in a substantial cost to the Department that may be offset by funding from the CDC. A more specific analysis of this cost and potential savings is detailed in *Question 22*.

Small Business Analysis

Under section 3 of the Regulatory Review Act, 71 P.S. § 745.3, a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many health care practitioners, health care facilities, laboratories, schools and child care group settings are small businesses.

Based on these Federal standards, the Department determined that a physician's office is a small business if it has $16 million or less in annual receipts, and a dentist's office, chiropractor's office, podiatrist's office, and optometrist's office is a small business if it has $9 million or less in annual receipts, and offices of all other

health care practitioners are considered a small business if they have $10 million or less in annual receipts. A veterinary office is a small business if it has $10 million or less in annual receipts. A clinical laboratory is a small business if it has $41.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of physician's offices, dentist's offices, chiropractor's offices, optometrist's offices, other health care practitioners, veterinary offices, or clinical laboratories that would be classified as a small business under this definition.

Using the same Federal standards, the Department determined that a hospital is a small business if it has $47 million or less in annual receipts, a long-term care nursing facility is a small business if it has $34 million or less in annual receipts, home health care services are a small business if they have $19 million or less in annual receipts, and all other health care services are considered a small business if they have $20.5 million or less in annual receipts. The Department estimates that 26 hospitals and 624 long-term care nursing facilities, would be considered to be a small business under the Federal standards. *See* PHC4. (2025). Financial Analysis 2023, Volume One. Retrieved from https://www.phc4.org/wp-content/uploads/fin2023report_volumeone.pdf; Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data; and GuideStar. Retrieved from https://www.guidestar.org/. The Department does not have sufficient data to determine the number of home health or other health care facilities that would meet the criteria for a small business.

Using the same Federal standards, the Department determined that an elementary or secondary school is a small business if it has $20 million or less in annual receipts. Based on total revenue data from the Pennsylvania Department of Education for school districts in this Commonwealth, the Department estimates that approximately 39% (295 out of 754) of school districts would be classified as a small business under this definition. *See* Pennsylvania Department of Education. (2023). AFR Data: Summary-Level. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/education/documents/schools/grants-and-funding/school-finances/summary-of-afr-data/afr-data-summary-level/finances%20afr%20revenues%202022-2023.xlsx. A college or university is a small business if it has $34.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of colleges or universities that would be classified as a small business under this definition. The Department also determined, using the same Federal standards, that a child care group setting is a small business if it has $9.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of child care group settings that would be classified as a small business under this definition.

The Department did not establish different criteria for small businesses. The Department's responsibility to protect public health through the prevention and control of diseases, infections and conditions necessitates compliance by all health care practitioners, facilities, laboratories, schools, colleges, universities, child care group settings, food handlers, veterinarians, and the general public, regardless of whether these entities and individuals are considered small businesses.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

Approximately 13 million Pennsylvanians, as well as visitors to this Commonwealth, will benefit as these proposed amendments will better protect the public from outbreaks and the spread of communicable diseases. These proposed amendments include enabling the Department to perform contact tracing and partner services to interrupt disease transmission in this Commonwealth, expanding the list of reportable diseases by health care practitioners and facilities, requiring health care providers to provide individuals who undergo HIV or STD testing with information about potential contact from the Department for partner services, and clarifying exclusion and readmission criteria for specific diseases, infections, and conditions for food handlers, health care

practitioners, students, children in child group settings, and those who have direct contact with students or children in a child group setting. Additionally, proposed amendments include updates to the immunization requirements of children in child care group settings to prevent the spread of diseases among school aged children in this Commonwealth, requiring prenatal examination by health care providers for Hepatitis C and HIV for early detection and clarifying and adding isolation and quarantine language for individuals and animals with a specific disease, infection or condition. Furthermore, laboratories will, under the proposed amendments, now have to report birth, gender, race, ethnicity, employer information and pregnancy status. Though this may require more work for the laboratories, this will benefit overall patient health by promoting health equity initiatives and accurate approaches to prevent disease spread.

The proposed rulemaking contains much needed amendments to the existing regulations to align with Federal and state standards. This includes adhering to specific CDC guidance for tuberculosis isolation requirements and coordinating the reporting of select agents or toxins without impinging on already established CDC processes. *See* Jensen, P., et al. (2005). "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005." *Morbidity and Mortality Weekly Report*, 54(RR-17). The Department is also proposing to amend the definition of select agents or toxins to coincide with the US Department of Health and Human Services and the US Department of Agriculture. Though establishing a birth defect registry is not required federally, Pennsylvania is one of the only states in the region that does not have a birth defect registry. Establishing a birth defect registry will allow the Department to track birth defects and congenital anomalies within the state, where in the state they are occurring and how often are they occurring, all of which can help the Department's prevention and referral efforts. Proposed amendments for consistency with other Pennsylvania state laws and regulations include the reporting and quarantine requirements under 3 Pa.C.S. § 2321(a) and (c) and various school definitions under sections 13 and 17 of the Public School Code of 1949 (24 P.S. §§ 13-1326 and 17-1703-A) as well as the Private Academic Schools Act (24 P.S. §§ 6701—02).

Specific proposed amendments that will benefit health care practitioners and health care facilities include amending the format of reporting cases § 27.21a referring to reporting of cases by health care practitioners and health care facilities which is now in a chart format, with an expanded list, that includes the manner and timeframe of reporting to the Department in alphabetical order by disease, infection or condition. This will allow for an ease of readability and efficient accessibility of information. The Department proposes a similar amendment for clinical laboratories in § 27.22 which refers to reporting of cases by clinical laboratories. While expanding the list of diseases, infections, or conditions that a hospital or laboratory must report on is expected to result in a cost initially to health care facilities and the laboratories, it is anticipated that the long-term benefits of reduced disease transmissibility affecting both health care facilities, laboratories, and patients will outweigh these costs.

The Department also proposes to require health care practitioners and health care facilities to report treatment of tuberculosis and select sexually transmitted diseases (STDs) through PA-NEDSS. Though this may result in additional costs up front in terms of time for the health care practitioners and health care facilities to report this data, this surveillance is needed to confirm the start of treatment for tuberculosis while also determining if select cases of STDs are new and part of an emerging outbreak benefitting health care practitioners and the health care facilities in the long run. Additionally, the proposed amendment that will now require health care practitioners and health care facilities to participate in the Department's immunization information system, unless a patient declines in writing, may result in initial costs as this was previously on a volunteer basis, but will allow for better care of a patient by a health care practitioner or facility by providing access to the patient's vaccination status.

Veterinarians will also benefit from proposed amendments to the reporting requirements of diseases, conditions and infections to the Department. The proposed amendments will refine the specific diseases, infections, or

conditions in domesticated animals that veterinarians have to report to the Department, preventing duplicate reporting to the Department of Agriculture.

Schools and child care group settings will also benefit from specific proposed amendments specifically pertaining to exclusion and readmission criteria for workers, volunteers, food handlers and enrolled students and children. The Department is proposing to update and clarify the exclusion and readmission criteria for individuals while adding requirements for exclusion of close contacts with those with a specific disease, infection or condition. The clarity provided through these amendments will ensure that individuals and food handlers in schools and child care group settings know when to stay home if they are experiencing certain symptoms. This will prevent disease spread and interruption of the normal day to day run of a school or child care group setting.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Health care practitioners and health care facilities

Over 400,000 health care practitioners and over 6,000 health care facilities in this Commonwealth will be impacted by the proposed rulemaking. These practitioners and facilities will be positively impacted by proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.21a, which will make it easier for these practitioners and facilities to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All health care practitioners and health care facilities will be financially impacted by proposed amendments to § 27.21a, which will increase the number of diseases, infections and conditions that practitioners and facilities will have to report to the Department's electronic disease surveillance system (PA-NEDSS). All practitioners and facilities are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients seen at a location, the number of reportable diseases diagnosed at each location, and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by the proposed addition of § 27.33a, which will require reporting treatment provided to all suspected or confirmed cases of tuberculosis and certain sexually transmitted diseases. Practitioners and facilities will be required to report to the Department's already-existing electronic disease surveillance system or to the local health department. Practitioners and facilities that electronically report will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the

number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Some health care practitioners and health care facilities, and individuals authorized by law to administer immunizations, will be financially impacted by the proposed addition of § 27.36 (relating to reporting immunization delivery), which will require these practitioners, facilities and individuals to report each immunization administration in all counties of this Commonwealth, except Philadelphia County, to the Department's designated immunization information system. Philadelphia County is excluded from this requirement as they have their own reporting system already in place. The Department estimates that approximately 21,000 health care practitioners, facilities and individuals will need to comply with this new requirement. Out of this number, 16,250 are already voluntarily reporting to the Department's immunization electronic registry system (PIERS). The 4,750 not currently reporting will need to establish a process for reporting to PIERS, either electronically or manually, which may require additional staff or IT support and will vary depending on factors such as the number of immunizations that are being reported and who is hired to perform this function. The Department does not currently have sufficient data to estimate the financial impact to these 4,750 practitioners, facilities and individuals. For this reason, the Department is estimating no overall financial impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by the proposed addition of § 27.37 (relating to reporting birth defects and congenital anomalies) which will require practitioners and facilities to report certain birth defects and congenital anomalies to the Department. Specifically, practitioners and facilities will need to establish a system for reporting birth defects to the Department's newly created electronic birth defects registry. This may involve creating an electronic system for automated reporting or allocating staff to manually submit data to the Department's birth defects registry, the cost of which will vary depending on factors such as the number of patients with reportable birth defects and the type of individual hired to perform this function. The Department does not have sufficient data to estimate the cost of creating an electronic system or the amount of staff time needed for such reporting. For this reason, the Department is estimating no overall fiscal impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by new proposed § 27.71a, which will update the exclusion and readmission requirements for health care practitioners. The Department does not propose to increase the total number of entries which require exclusion; however, the proposed amendments do remove a broad symptom of disease from the exclusion requirements and replace it with a specific disease. Health care practitioners may experience fewer exclusions because of this change, potentially resulting in savings in decreased time away from work. Health care facilities may lose less staff time to exclusions under this new proposed section, potentially resulting in savings. The Department cannot accurately estimate the savings of this proposed change due to the unpredictability of the number of symptomatic exclusions compared to illnesses for individual food handlers or each entity employing food handlers.

Health care practitioners within the scope of their practice who attend, treat or examine pregnant individuals may be financially impacted by the proposed addition of §§ 27.99a and 27.99b (relating to prenatal examination for hepatitis C and prenatal examination for HIV), which will require them to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. The factors in determining fiscal impact will vary depending on each practitioner's practice, such as additional paperwork to order the blood draw, additional time from staff drawing blood or costs in submitting the sample to a laboratory for testing. Costs for drawing the blood sample may be offset, in some cases, by the pregnant individual's insurance plan or the pregnant individual paying out-of-pocket for the test. Administrative costs, such as paperwork, may be

absorbed by the practitioner as a cost of business. Due to these varying factors, the Department is not able to estimate a specific cost or savings impact. The Department is therefore estimating no overall cost as a result of this requirement.

Laboratories

All 9,589 clinical laboratories in this Commonwealth will be impacted by the proposed amendments. These laboratories will benefit from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.22, which will make it easier for them to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All clinical laboratories will be financially impacted by proposed amendments to § 27.22(b) and (c), which will increase the number of diseases, infections and conditions, as well as the types of data, that they will have to report to the Department. All clinical laboratories are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Clinical laboratories that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of clinical laboratories that electronically and manually report to estimate the financial impact to these practitioners and facilities. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Clinical, research or commercial laboratories, in this Commonwealth, that are registered with the Federal Select Agent Program (FSAP) to possess, use or transfer select agents or toxins will be impacted by the addition of proposed § 27.22a (relating to reporting of select agents or toxins), which will require these laboratories to report a detected release, exposure, loss or theft of a select agent or toxin to tBOL. Currently, there are six laboratories to whom this requirement will apply. These laboratories will need to add the Department to any existing process or system they currently have in place for complying with already-existing requirements by FSAP. The Department does not have sufficient data to estimate the cost of this task but anticipates that any cost would be minimal. For this reason, the Department is estimating no overall fiscal impact for this requirement.

Schools, Colleges, Universities and Childcare Group Settings

All 500 school districts, which range in size from approximately 200 students to more than 140,000 students, and more than 160 brick-and-mortar charter schools and 14 cyber charter schools, which educate approximately 135,000 students, and the approximately 199,000 individuals employed by public and private schools, will be impacted by the proposed amendments. Approximately 400 colleges and universities in this Commonwealth, and 633,991 students and 161,146 employees in those settings, will be impacted by the proposed amendments. Additionally, all 6,378 childcare group settings in this Commonwealth, and 96,197 individuals employed in those settings, will be impacted by the proposed amendments. Schools, colleges, universities and childcare group settings will be positively impacted from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for exclusion and readmission requirements in proposed § 27.71a, which will make it easier to comply with the regulations, which may result in cost savings

to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All schools, colleges, universities and childcare group settings may be financially impacted by proposed amendments to § 27.71a, which will add exclusion and readmission requirements for 18 diseases, infections and conditions to the existing list. The proposed amendments, including the addition of exclusion and readmission requirements for 18 new diseases, infections and conditions, align with current recommendations from the American Academy of Pediatrics (AAP) and will ensure the health and safety of students and staff attending these entities. However, these entities may also be financially impacted by an increase in staff and student absences from this expansion, necessitating the need, for example, substitute teachers. Because this cost will vary based on the number of illnesses and time missed, the Department is not able to estimate a specific cost. For that reason, the Department is estimating no overall fiscal impact for this requirement.

All schools may be impacted by the proposed addition of § 27.60c, which will require a school to provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises or attending a school function. Compliance with this requirement may result in a time disruption to schools, which will vary based on the disease, infection of condition being investigated. Because of the inability to estimate a specific cost, the Department is estimating no overall fiscal impact for this requirement.

Veterinarians

Approximately 3,200 veterinarians in this Commonwealth will be impacted by the proposed amendments. All veterinarians will be positively impacted by the proposed addition of specific diseases, infections and conditions in § 27.24a (relating to reporting of cases by veterinarians). The Department consulted with the Pennsylvania Department of Agriculture, and is proposing to limit the reporting of diseases, infections and conditions, which may be transmitted from animals to humans, to the Department that are already not being reported to the Department of Agriculture to prevent double reporting. This may result in a cost savings through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

General Public

The general public, consisting of approximately 13 million individuals in this Commonwealth, will be impacted by the proposed amendments. The public will be positively impacted by proposed amendments to expand various reporting requirements by health care practitioners, health care facilities and laboratories, as this information will be utilized by the Department to conduct investigations and take appropriate measures to protect public health. Other proposed amendments clarifying existing requirements, such as the disease control measures that the Department may take under § 27.60 (relating to disease control measures), will also protect the public health by ensuring that the Department may act appropriately and quickly when needed, which will result in benefits such as preventing the spread of a disease, condition or illness. This could result in cost savings to the public, such as a reduction in health care expenses and less missed time from work. Factors involved in calculating this cost savings will vary depending on the circumstances. For that reason, the Department is estimating no fiscal savings to the general public due to these amendments.

Additional proposed requirements relating to exclusion and readmission of students, children, staff, food handlers and health care practitioners may result in a financial impact due to individuals missing time from work or school, but will prevent the spread of contagious diseases, infections and conditions in settings such as schools, colleges, universities, and child care group settings. However, the Department made an effort, where appropriate, to remove the need for health care provider verification for readmission, which will alleviate the time and monetary burden for parents, guardians, and other individuals potentially impacted by the proposed exclusion requirements. Factors involved in calculating cost and savings related to time vary depending on the circumstances. Therefore, the Department is estimating no overall fiscal impact for these requirements.

Pregnant individuals will be impacted by the proposed addition of §§ 27.99a and 27.99b, which will require health care practitioners acting within the scope of their practice who attend, treat or examine pregnant individuals to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. The estimated cost to pregnant individuals will vary depending on health insurance plans. For example, these individuals may need to pay a co-pay for an office visit as well as for the blood draw. Co-pays for an office visit typically average $25 for a primary care physician and $30 for an obstetrician. *See* Machlin, S. & Mitchell, E. (2018). Statistical Brief #517: Expenses for Office-Based Physician Visits by Specialty and Insurance Type, 2016. Retrieved from https://meps.ahrq.gov/data_files/publications/st517/stat517.shtml. The cost for the actual blood draw will vary as well, depending on insurance coverage, and the method utilized for the draw. Hepatitis C and HIV may be tested through one blood draw or the submission of separate blood draws for each condition. Quest Diagnostics, for example, charges approximately $62 for a single test for hepatitis C and $85 for HIV, and $282 for a combined blood draw that tests for both. *See* Quest Diagnostics. (2025). Hepatitis C Test with Confirmation. Retrieved from https://www.questhealth.com/product/hepatitis-c-test-with-confirmation-8472M.html; Quest Diagnostics Inc. (2025). HIV 1 & 2 Test with Confirmation. Retrieved from https://www.questhealth.com/product/hiv-1-2-test-with-confirmation-91431M.html; and Quest Diagnostics Inc. (2025). STD Screening Test Panel – Expanded. Retrieved from https://www.questhealth.com/product/std-screening-panel-expanded-37328M.html. On the other hand, the estimated lifetime cost of treatment for hepatitis C ranges from $26,400 to $84,000 and for HIV ranges from $420,285 to over $1 million. *See* University of Pennsylvania. (2018). Cost-effective Screening and Treatment of Hepatitis C. Retrieved from https://ldi.upenn.edu/our-work/research-updates/cost-effective-screening-and-treatment-of-hepatitis-c/; Henry, B. (2018). "Drug Pricing & Challenges to Hepatitis C Treatment Access." *J. Health Biomed Law* 14, 265-83; and Bingham, A., et al. (2021). "Estimated Lifetime HIV-Related Medical Costs in the United States." *Sex. Transmitted Dis.* 48(4), 299-304. However, these additional tests will positively impact these individuals and their unborn fetuses by ensuring early, preventative treatment is provided to improve the health outcome of both the pregnant individual and the child, which may result in a cost savings to these individuals and their children. Because a specific cost and savings estimate will vary depending on the number of pregnant individuals being tested, as well as their specific insurance plans, the Department is estimating no fiscal cost of savings to these individuals.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Department does not anticipate any specific costs or savings to local governments. All 11 local health departments will be impacted by proposed amendments to §§ 27.32d and 27.32e, which will allow local health authorities to have access to, review and conduct audits of HIV-related patient records. This proposed amendment will allow for local health department disease investigation personnel to conduct all disease investigations within their jurisdiction, where they are the primary investigator, potentially minimally increasing the workload for those personnel. Local health departments will be impacted by proposed

amendments to § 27.42a, which will extend the deadline to submit a case investigation report from each case investigation that results in a confirmed reportable disease. The proposed 2-day extension will give local health departments more time to complete reports. Local health departments will be impacted by proposed amendments to § 27.67 (relating to movement of persons and animals subject to isolation or quarantine by action of a local health authority or the department), which will require local health departments to grant permission for the interstate transportation of a person or animal under isolation or quarantine if involved. This proposed amendment will ensure that local health departments are informed and involved in such cases of interstate transportation.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

Additional submission of specimens, isolates and cultures

The Department will incur costs as a result proposed amendments to § 27.22(l), which will require a clinical laboratory, if it suspects the presence of certain select agents or toxins, to submit specimens or cultures to BOL or another laboratory designated by BOL. There would be a cost to BOL, which bears all of the associated costs for courier pick-up and transport of the suspected specimens, and for the testing, and for shipping presumptive positive specimens to the CDC for confirmatory testing. The Department is not able to estimate a specific cost, as this would depend on the number of specimens or cultures sent to BOL. However, courier costs vary by county location, currently ranging from $50 to $90 plus a fuel surcharge. BOL estimates an average cost of $75/specimen, which is typically delivered next day. During emergent events (*e.g.* H5 avian influenza), BOL requests express delivery (same day pickup and drop-off at $2.25/mile). In that scenario, a package from Erie County would cost over $900, for example.

Birth Defects Registry

The Department will incur costs as a result of new proposed § 27.37, which will require the Department to create a birth defects registry for the reporting of certain birth defects and congenital anomalies. To estimate the cost of this new proposed requirement, the Department consulted with other states, including New Jersey, Ohio and Florida. The Department determined through these and other internal discussions that the cost will vary depending on whether the Department chooses to add a module to its already existing newborn screening system or to build a new system.

The Department estimates that the cost to add a module to its already existing newborn screening system would result in a one-time cost of $150,000 plus an estimated $30,000 annually thereafter to cover system maintenance and an estimated $40,000 to $100,000 for hosting data depending on what data is collected and stored. The estimated startup and maintenance cost, not including staff, is less than New Jersey, who indicated they budget for $250,000 to $280,000 annually for operation of their modification and maintenance of their birth registry system.

Once the birth defects registry is established, the Department will need to hire staff to manage it. The Department estimates a total of $1,523,977 for staff for the first year of operation. This estimate includes an estimated $1,512,877 for salaries and benefits and initial operating costs of $11,100. The breakdown includes two IT contractors for project management and internal support at an estimated cost of $220,000 per contractor's salary, one full-time public health program administrator with an estimated starting salary of

$66,000 to $100,000, plus benefits, who will be tasked with creating protocols and documents, one full-time epidemiologist and one full-time epidemiology research associate for support and investigative work, conducting data analytics, and curating reports from the data collected. The Department estimates the starting salary for these two individuals to be $112,000 to $170,000 each, plus benefits. Lastly, the total costs include one part-time administrative person, for support, at a salary of $44,000 to $67,000, plus benefits, dependent upon experience.

The Department also estimates that it will incur a cost for education and training of staff in the use of the birth defects registry. The Department estimates this cost to be approximately $20,000 to $30,000 at least for the first two years and then can be scaled back over time.

The Department anticipates applying for a CDC grant to offset the initial start-up and ongoing costs of the birth defects registry. This amount varies. Although it is not guaranteed, based on conversations with other states, the Department believes that it could receive between $300,000 to $600,000 from this grant, assuming that the grant is approved and funds are available.

The Department proposes delaying the effective date of proposed § 27.37 to accommodate the development and full implementation of the birth defects registry. Section 27.37 will become effective 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, record keeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The Department anticipates that the following requirements will result in either a one-time update to health care practitioners, health care facilities and clinical laboratories' internal automated reporting systems linked to PA-NEDSS, or the allocation of additional staff time to manually enter data for PA-NEDSS.

- Proposed § 27.21a requires health care practitioners and health care facilities to report an additional 73 diseases, infections and conditions to the Department.
- Proposed § 27.22 requires clinical laboratories to report the presence of an additional 53 diseases, infections and conditions to the Department.

Additionally, the proposed amendments to § 27.24a will require veterinarians to report an additional four diseases, infections and conditions found in animals to the Department. The Department has made efforts to minimize double reporting by only adding a few specific diseases, infections and conditions that are not currently reported to the Pennsylvania Department of Agriculture.

New proposed § 27.22a will require clinical, research or commercial laboratories that possess, use or transfer select agents or toxins to report release, exposure, loss or theft of such to the Department. The Department has modeled its required data elements after the FSAP requirements so that a laboratory experiencing such an event can send the same report to FSAP and the Department and comply with this proposed amendment.

New proposed § 27.4a will require hospitals to report emergency department visit data to the Department. All hospitals are already voluntarily reporting this data to the Department.

New proposed § 27.33a will require health care practitioners and health care facilities to report treatment of six sexually transmitted diseases as well as tuberculosis to the Department.

New proposed § 27.33a will require health care practitioners and health care facilities to report animal bites, scratches or contamination of open wounds or mucous membranes to the Department.

(22a) Are forms required for implementation of the regulation?

Yes.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

Proposed § 27.33b (relating to reporting cases of animal bites, scratches or contamination of open wounds or mucous membranes) will require a health care practitioner or health care facility to report human exposure to animal saliva or neural tissue through a bite, scratch or contamination of an open wound or mucous membrane. Unless otherwise directed, this report is to be made on a form prescribed by the Department. *See* Attachment A.

The Department proposes to amend § 27.32b(b) (relating to confidential and anonymous testing) to remove the words "counseling and" which reflects a change in the form that is already used to report anonymous HIV test results. *See* Attachment B.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year (2025-2026)	**FY +1 Year (2026-2027)**	**FY +2 Year (2027-2028)**	**FY +3 Year (2028-2029)**	**FY +4 Year (2029-2030)**	**FY +5 Year (2030-2031)**
SAVINGS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0

Local Government	0	0	0	0	0	0
State Government	0	384,903	1,836,680	1,921,069	2,009,677	2,111,716
Total Costs	0	384,903	1,836,680	1,921,069	2,009,677	2,111,716
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 (2021-2022)	FY -2 (2022-2023)	FY -1 (2023-2024)	Current FY (2024-2025)
Bureau of Epidemiology	69,857,743	91,991,291	55,228,166	44,425,132
Bureau of Laboratories	22,159,276	21,342,215	18,456,034	23,757,786
Bureau of Communicable Diseases and Immunizations	109,247,867	88,780,444	117,262,580	140,045,148
Bureau of Community Health Systems	80,230,629	93,777,921	102,398,831	106,457,429
Bureau of Emergency Preparedness and Response	52,176,486	37,719,089	27,998,143	50,260,771
Bureau of Family Health	45,526,787	51,017,853	50,731,264	69,465,114
Bureau of Health Statistics	17,373,440	19,913,837	22,504,275	23,884,502
Deputy Secretary for Quality Assurance	42,087,713	43,460,710	44,991,628	49,490,688
State Laboratory Appropriation	6,261,020	6,854,871	8,056,299	8,241,951
Newborn Screening Appropriation	4,825,659	7,164,545	5,366,080	5,635,041

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

Based on Federal standards, the Department determined that a physician's office is a small business if it has $16 million or less in annual receipts, and a dentist's office, chiropractor's office, podiatrist's office, and optometrist's office is a small business if it has $9 million or less in annual receipts, and offices of all other health care practitioners are considered a small business if they have $10 million or less in annual receipts. A veterinary office is a small business if it has $10 million or less in annual receipts. A clinical laboratory is a small business if it has $41.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of physician's offices, dentist's offices, chiropractor's offices, optometrist's offices, other health care practitioners, veterinary offices, or clinical laboratories that would be classified as a small business under this definition.

Using the same Federal standards, the Department determined that a hospital is a small business if it has $47 million or less in annual receipts, a long-term care nursing facility is a small business if it has $34 million or less in annual receipts, home health care services are a small business if they have $19 million or less in annual receipts, and all other health care services are considered a small business if they have $20.5 million or less in annual receipts. The Department estimates that 26 hospitals and 624 long-term care nursing facilities, would be considered to be a small business under the Federal standards. *See* PHC4. (2025). Financial Analysis 2023, Volume One. Retrieved from https://www.phc4.org/wp-content/uploads/fin2023report_volumeone.pdf; Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data; and GuideStar. Retrieved from https://www.guidestar.org/. The Department does not have sufficient data to determine the number of home health or other health care facilities that would meet the criteria for a small business.

Using the same Federal standards, the Department determined that an elementary or secondary school is a small business if it has $20 million or less in annual receipts. Based on total revenue data from the Pennsylvania Department of Education for school districts in this Commonwealth, the Department estimates that approximately 39% (295 out of 754) of school districts would be classified as a small business under this definition. *See* Pennsylvania Department of Education. (2023). AFR Data: Summary-Level. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/education/documents/schools/grants-and-funding/school-finances/summary-of-afr-data/afr-data-summary-level/finances%20afr%20revenues%202022-2023.xlsx. A college or university is a small business if it has $34.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of colleges or universities that would be classified as a small business under this definition. The Department also determined, using the same Federal standards, that a child care group setting is a small business if it has $9.5 million or less in annual receipts. The Department does not have sufficient data to determine the number of child care group settings that would be classified as a small business under this definition.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

Proposed § 27.21a will increase the number of diseases, infections and conditions that practitioners and facilities will have to report to the Department's electronic disease surveillance system (PA-NEDSS). All practitioners and facilities are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department.

Proposed § 27.22(b) and (c) will increase the number of diseases, infections and conditions, as well as the types of data, that clinical laboratories will have to report to the Department. All clinical laboratories are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Clinical laboratories that manually report will need to allocate additional resources, including staff time, to submit data to the Department.

Proposed § 27.22a will require clinical, research and commercial laboratories that are registered with FSAP to possess, use or transfer select agents or toxins to report a detected release, exposure, loss or theft of a select agent or toxin to BOL. Currently, there are six laboratories to which this requirement will apply and will require these laboratories to add the Department to any existing process or system they currently have in place for complying with already-existing requirements by FSAP.

Proposed § 27.24a will require veterinarians to report specific diseases, infections and conditions. The Department consulted with the Pennsylvania Department of Agriculture, and is proposing to limit the reporting of diseases, infections and conditions, which may be transmitted from animals to humans, to the Department that are already not being reported to the Department of Agriculture to prevent double reporting.

Proposed § 27.33a which will require health care practitioners and facilities to report treatment provided to all suspected or confirmed cases of tuberculosis and certain sexually transmitted diseases. Practitioners and facilities will be required to report to the Department's already-existing electronic disease surveillance system or to the local health department. Practitioners and facilities that electronically report will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department.

Proposed § 27.36 will require health care practitioners and health care facilities, and individuals authorized by law to administer immunizations, to report each immunization administration in all counties of this Commonwealth, except Philadelphia County, to the Department's designated immunization information system. Philadelphia County is excluded from this requirement as they have their own reporting system already in place. The Department estimates that approximately 21,000 health care practitioners, facilities and individuals will need to comply with this new requirement. Out of this number, 16,250 are already voluntarily reporting to the Department's immunization electronic registry system (PIERS). The 4,750 not currently reporting will need to establish a process for reporting to PIERS, either electronically or manually, which may require additional staff or IT support.

Proposed § 27.37 will require all health care practitioners and health care facilities to report certain birth defects and congenital anomalies to the Department. These practitioners and facilities will need to establish a system for reporting birth defects to the Department's newly created electronic birth defects registry. This may involve creating an electronic system for automated reporting or allocating staff to manually submit data to the Department's birth defects registry.

(c) A statement of probable effect on impacted small businesses.

See answer to Question 15. Small businesses will be affected by these regulations in the same manner as other facilities that are not small businesses.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

See answer to Question 26. The Department did not identify any less costly alternative that would be consistent with public health and safety.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

No special provisions have been developed as this proposed rulemaking applies to all health care practitioners, health care facilities, clinical laboratories, schools, colleges, universities, childcare group settings, veterinarians, and the general public in this Commonwealth.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

During stakeholder engagement, some stakeholders requested that the Department amend proposed § 27.23 (relating to reporting of cases by persons in charge of child care group settings) to definitively require reporting of suspected or known cases of the diseases, infections or conditions, listed in § 27.21a, during a public health emergency or to prevent one. The Department, after considering current and past practices, chose to not adopt the suggestion as this would require the Department to ask every child care group center to submit identified reportable diseases during a public health emergency, which could be a logistical burden and result in unnecessary data collection. However, the Department chose to strengthen the language after hearing the suggestion, by giving the Department the ability to require child care group settings to report cases, when the Department deems it necessary, during a public health emergency instead of merely requesting it from them. Granting a child care group setting discretionary authority to require such reporting in select circumstances negates the aforementioned risk and represents the least burdensome acceptable alternative.

Some stakeholders also expressed concerns regarding the removal, in proposed § 27.77, of the incorporation by reference of the ACIP's Child and Adolescent Immunization Schedule standards for immunity requirements as opposed to the proposed list of immunization requirements for children in a child care group setting. The Department is not permitted to delegate its authority to make rules and regulations by adopting future recommendations. *See Protz v. Workers' Compensation Appeal Board*, 161 A.3d 827 (Pa. 2017). Therefore, removing the incorporation by reference to ACIP represents the least burdensome alternative.

The Department considered feedback from stakeholders regarding the Department's proposed requirement, in § 27.36 (relating to reporting immunization delivery) for health care practitioners, health care facilities, or those authorized to administer immunizations to generate a vaccine administration report within 30 days of administration. The stakeholders suggested that this timeframe be reduced as this may be too large of a time window. However, after consideration, the Department chose to keep the vaccine administration report within 30 days of administration as this proposed language is based on Philadelphia County's requirement that is currently in place. Mirroring requirements with Philadelphia will ensure that the entire Commonwealth is consistent. Additionally, Philadelphia has had this requirement for more than 10 years, and it has proven to be a successful model and thus, represents the least burdensome acceptable alternative.

Furthermore, it was suggested by some stakeholders to include reporting of pinworm (enterobiasis) in § 27.23 by persons in charge of child care group settings. After consideration, the Department chose not to add pinworm to this section as pinworm is not a nationally notifiable disease identified by the CDC, and after

reviewing other states, it does not appear to be a common requirement at the state level either. Pinworm is relatively common and treatable. The main public health risk would be mostly in an institutional setting (healthcare, prisons, etc.), which would be captured through requirements elsewhere in the proposed regulations, should an outbreak occur. Thus, the least burdensome acceptable alternative was chosen.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

a) Less stringent compliance or reporting requirements were not considered.
b) Less stringent schedules or deadlines for compliance or reporting were not considered.
c) Consolidation or simplification of compliance or reporting requirement were not considered.
d) The establishment of performance standards for small businesses were not considered.
e) The exemption of small business from all or any part of the proposed regulations were not considered.

(28) If data is the basis for this regulation, please provide a description of the data, explain <u>in detail</u> how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The Department did not rely on data as the basis for this regulation.

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period:

45 days after publication as proposed regulations in the *Pennsylvania Bulletin*.

B. The date or dates on which any public meetings or hearings will be held:

The Department engaged with relevant stakeholders, potentially impacted agencies and local health departments in the spring and summer of 2024.

The State Advisory Health Board approved the proposed amendments at a public meeting held on July 17, 2025.

C. The expected date of delivery of the final-form regulation: March 2028

D. The expected effective date of the final-form regulation:

The final-form regulations will become effective upon their publication in the *Pennsylvania Bulletin* as final regulations, except that proposed § 27.37 (relating to reporting of birth defects and congenital anomalies) will become effective 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry.

E. The expected date by which compliance with the final-form regulation will be required:

Upon publication as final form, except proposed § 27.37 (relating to reporting of birth defects and congenital anomalies), which will have a delayed effective date to accommodate the development and full implementation of the new birth defects registry. Section 27.37 will become effective 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry.

F. The expected date by which required permits, licenses or other approvals must be obtained:

N/A

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department regularly reviews the validity and efficacy of its regulations and will continue to do so in the future and as needs arise.

Attachment A – Animal Bite Report Form

Pennsylvania Department of Health

ANIMAL BITE REPORT

Confidential

SHC/HD: _____
SHC/HD Fax: _____
Date Rec'd by SHC/HD: _____
Date Sent to Dog Warden: _____

Form must be completed by the provider and faxed to the appropriate State Health Center (SHC)/local health department (HD) within 24 hours. For in state victims, fax to the victim's home county. For out of state victims, fax to the treatment facility's county. Fax numbers can be found here: www.health.pa.gov.

VICTIM INFORMATION

Last name _____ First name _____ M.I. _____

Date of birth _____ If minor, parent name _____

Street address _____

City _____ State _____ Zip _____ County _____

Phone _____ Email address _____

Victim address for next 10 days, if different from above _____

OWNER INFORMATION, if known and different than victim. If same as Victim, select: ☐

Last name _____ First name _____ M.I. _____

Street address _____

City _____ State _____ Zip _____ County _____

Phone _____ Email address _____

Owner address for next 10 days, if different from above _____

ANIMAL INFORMATION

Type: ☐ Dog ☐ Cat ☐ Other: _____ Status: ☐ Pet ☐ Stray ☐ Wild Sex: ☐ Male ☐ Female

Breed _____ Color _____ Age _____

Vaccinated: ☐ Yes ☐ No ☐ Unknown Date of Last Rabies Vaccine: _____

Veterinarian: _____
Name Address Phone

INCIDENT INFORMATION

Incident date: _____ Incident type: ☐ Bite ☐ Scratch ☐ Other: _____ Part of body: _____

Incident location: ☐ Owner's home ☐ Victim's home ☐ Other: _____

What caused the incident? Describe circumstances: _____

_____

_____

Pursuant to 3 P.S. § 459-505-A, "all known incidents of dog attacks shall be reported to the State dog warden, who shall investigate each incident and notify the Pennsylvania Department of Agriculture if a dog has been determined to be dangerous." The Pennsylvania Department of Health is mandated to share the above information with the State dog warden when a dog bite attack is reported.

TREATMENT INFORMATION - Not shared with State dog warden/Department of Agriculture.

Treatment date: _____ Type of wound: ☐ Superficial ☐ Deep ☐ Other: _____

Treatment: ☐ Cleansed ☐ Antibiotic ☐ Tetanus ☐ HRIG site*: _____ ☐ HDCV/PCEV (vaccine) site^: _____

*HRIG - infiltrate wound(s) with full dose, if possible, inject remaining volume in a site distant from vaccine (NO GLUTEUS).
^HDCV/PCEV - use deltoid, or thigh in children (NO GLUTEUS)

Treatment Provider: _____
Provider Name Facility Phone

Form Completed by: _____
Name Phone Number Date

Revised 10.28.24

Attachment B – HIV Test Form

HIV Test Form

pennsylvania DEPARTMENT OF HEALTH

Agency Information

Agency

Program

Form ID

Form ID should automatically populate. If not, use the first and third letter of the first and last name followed by the 8-digit date of birth. Example: Jane Doe 01/01/2000 = JNDE01012000

Session Date

Program Announcement

PS24-0047

Site Name

Client Information

Local Client ID (optional)

Year of Birth (1800 if unknown)

Client State (USPS abbreviation)

Client County (3-digit FIPS code)

Client Zip Code

Client Ethnicity

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Unknown
- ○ Declined to answer

Client Race (check all that apply)

- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Not specified
- ☐ Declined to answer
- ☐ Unknown

Client Sex

○ Male ○ Female

Has the client ever previously been tested for HIV?

○ No ○ Yes ○ Don't know

PrEP Awareness and Use

Has client ever heard of PrEP (pre-exposure prophylaxis)?

○ No ○ Yes

Is the client currently taking daily PrEP medication?

○ No ○ Yes

Has the client used PrEP anytime in the last 12 months?

○ No ○ Yes

Priority Populations

In the past 5 years, has the client had sex with a male?

○ No ○ Yes

In the past 5 years, has the client had sex with a female?

○ No ○ Yes

In the past 5 years, has the client injected drugs or substances?

○ No ○ Yes

Final Test Information

HIV Test Election

○ Confidential ○ Anonymous ○ Test not done

Test Type (select one only)

- ○ CLIA-waived point-of-care (POC) rapid test
- ○ Laboratory-based test

POC Rapid Test Result

○ Preliminary positive ○ Positive ○ Negative

○ Discordant ○ Invalid

Laboratory-Based Test Result

- ○ HIV-1 Positive
- ○ HIV-1 Positive, possible acute
- ○ HIV-2 Positive
- ○ HIV Positive, undifferentiated
- ○ HIV-1 Negative, HIV-2 inconclusive
- ○ HIV-1 Negative
- ○ HIV Negative
- ○ Inconclusive, further testing needed

Result Provided to Client?

○ No ○ Yes ○ Yes, from another agency

Additional Tests

Was the client tested for co-infections?

○ No ○ Yes

Syphilis

Was the client tested?

○ No ○ Yes

Result:

○ Newly identified ○ Not infected ○ Not known

Gonorrhea

Was the client tested?

○ No ○ Yes

Result:

○ Positive ○ Negative ○ Not known

Chlamydia

Was the client tested?

○ No ○ Yes

Result:

○ Positive ○ Negative ○ Not known

Hepatitis C

Was the client tested?

○ No ○ Yes

Result:

○ Positive ○ Negative ○ Not known

Supplemental HIV Test

Show Supplemental HIV Test 1

(Supplemental tests are not reported to CDC)

○ No ○ Yes

Essential Support Services

Health benefits navigation and enrollment

Screened for need:
No Yes

Need determined:
No Yes

Provided or referred:
No Yes

Evidence-based risk reduction intervention

Screened for need:
No Yes

Need determined:
No Yes

Provided or referred:
No Yes

Behavioral health services

Screened for need:
No Yes

Need determined:
No Yes

Provided or referred:
No Yes

Social services

Screened for need:
No Yes

Need determined:
No Yes

Provided or referred:
No Yes

Local Use Fields (Optional)

Local Use Field 1

Local Use Field 2

Local Use Field 3

Local Use Field 4

Local Use Field 5

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

Independent Regulatory
Review Commission

June 4, 2026

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General	Copy below is here by certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or Independent Agencies.
BY: Amy M. Elliott (DEPUTY ATTORNEY GENERAL)	Department of Health (AGENCY)	BY: Eddie J. Adelson .
5/20/2026 DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-242 DATE OF ADOPTION:	3/25/2026 DATE OF APPROVAL
☐ Check if applicable Copy not approved. Objections attached.	Debra L. Bogen MD BY: Debra L. Bogen, MD, FAAP TITLE: Secretary of Health (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	☐ (Chief Counsel, Independent Agency) (Strike inapplicable title) Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

28 Pa. Code Chapter 27

COMMUNICABLE AND NONCOMMUNICABLE DISEASES

The Department of Health (Department), with the approval of the State Advisory Health Board (Board), proposes to amend 28 Pa. Code Chapter 27 (relating to communicable and noncommunicable diseases) to read as set forth in Annex A.

Effective Date

The final-form regulations will become effective upon their publication in the *Pennsylvania Bulletin* as final regulations, except proposed § 27.37 (relating to reporting of birth defects and congenital anomalies), which will have a delayed effective date to accommodate the development and full implementation of the new birth defects registry. Section 27.37 will become effective 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry. A sunset date will not be imposed. The Department regularly reviews the validity and efficacy of its regulations and will continue to do so in the future and as needs arise. When the regulations are promulgated as final form, the Department will provide technical assistance and outreach to the regulated community to assist with implementation.

Public Comment

Interested persons are invited to submit comments, suggestions or objections to the proposed regulations within 45 days after publication of this notice in the *Pennsylvania Bulletin*. The Department prefers that comments, suggestions, or objections be submitted via email at: RA-DHCHAPTR27PROPREG@pa.gov. Persons without access to email may submit comments, suggestions or objections to Theresa Kash at the following address: 625 Forster Street, 8th Floor West, Health and Human Services Building, Harrisburg, PA, 17120, (717) 547-3317. Persons with a disability may submit questions in alternative format such as by audio tape, Braille, or by using V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800)

654-5984TT. Persons who require an alternative format of this document may contact Theresa Kash at the above email, address or telephone number so that necessary arrangements can be made. Comments should be identified as pertaining to proposed rulemaking 10-242 (communicable and noncommunicable diseases).

Statutory Authority

Section 16(a) of the Disease and Prevention Control Law of 1955 ("Act") (35 P.S. § 521.16(a)) gives the Board the authority to issue rules and regulations on the following: (1) the communicable and noncommunicable diseases that are to be reported; (2) the methods of reporting of diseases, the contents of reports and the health authorities to whom diseases are to be reported; (3) the communicable diseases which are subject to isolation, quarantine, or other control measures; (4) the duration of the periods of isolation and quarantine; (5) the enforcement of isolation and vaccination of persons and animals; (6) the immunization and vaccination of persons and animals; (7) the prevention and control of disease in public and private schools; (8) the regulation of carriers; (9) the advertisement of treatment, prophylaxis, diagnosis and cure of venereal diseases and the information which the physician must convey to persons being treated for a venereal disease in a communicable stage; (10) the prevention and control of noncommunicable diseases; and (11) any other matters it may deem advisable for the prevention and control of disease and for carrying out the provisions and purposes of the Act. Section 16(b) of the Act (35 P.S. § 521.16(b)) gives the Secretary of the Department the authority to review existing regulations and make recommendations to the Board for any changes the Secretary deems to be desirable.

The Department also has the general duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 ("Administrative

Code") (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code (71 P.S. § 532(g)) for this purpose. Section 2111(b) of the Administrative Code (71 P.S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease and for the protection of the lives and the health of the people of this Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department. Section 2106(a) of the Administrative Code (71 P.S. § 536(a)) also provides the Department with authority to declare diseases to be communicable, and to establish regulations for the prevention and control of disease. Section 2106(b) of the Administrative Code (71 P.S. § 536(b)) gives the Department the authority to establish and enforce quarantines to prevent the spread of diseases declared by law or by the Department to be communicable diseases. Section 2106(c) of the Administrative Code (71 P.S. § 536(c)) gives the Department the authority to administer and enforce the laws of this Commonwealth with respect to vaccination and other means of preventing the spread of communicable diseases.

The Board is required under section 2111(c.1) of the Administrative Code (71 P.S. § 541(c.1)) to make, and revise from time to time, a list of communicable diseases against which children shall be required to be immunized as a condition of attendance at any public, private, or parochial school, in this Commonwealth. This list shall be promulgated by the Secretary along with such regulations as may be necessary to ensure that such immunization be timely, effective and properly verified. Section 1421(c)(2) of the Public School Code of 1949 ("Public School Code") provides that the Secretary, in consultation with the Secretary of Education, has the authority to promulgate regulations implementing the school health program. The requirements for the school health program are set forth in Article XIV of the Public School Code, and

provide, among other things, that pupils are to be released from compulsory attendance when prevented from attending school by the laws or regulations of this Commonwealth. (24 P.S. § 14-1417). Section 1303a of the Public School Code (24 P.S. § 13-1303a) also requires school directors, superintendents, principals and other persons in charge of a school to ascertain that children, prior to admission to school for the first time, have been immunized against diseases listed by the Department, and reviewed by the Board. Regulations pertaining to vaccination of school age children exist primarily in 28 Pa. Code, Chapter 23. However, there is some overlap with these regulations in existing § 27.77 (relating to immunization requirements for children in child care group settings), which the Department proposes to amend below.

The Newborn Child Testing Act established a program within the Department to provide for screening tests of newborn children and follow-up services for certain diseases and conditions in the newborn child. (35 P.S. § 623). The Department has the authority, with the approval of the Newborn Screening and Follow-up Technical Advisory Board, to make changes to the reportable list of diseases and conditions under that act. (35 P.S. § 623(d)). The Department also has the authority to promulgate regulations to implement and administer the act. (35 P.S. § 625). These regulations exist primarily at 28 Pa. Code, Chapter 28. However, there is some overlap with these regulations in existing § 27.30 (related to reporting of cases of certain diseases in the newborn child), which the Department proposes to amend below.

The Pennsylvania Cancer Control, Prevention and Research Act (35 P.S. § 5636), enacted in this Commonwealth in 1980, requires reporting of cancer cases to the Department. The United States Cancer Registries Amendment Act was thereafter enacted in 1992 to provide funding and technical assistance to statewide cancer registries. *See* 42 U.S.C. §§ 280e—280e-5. The Federal law was amended in 2002 by the Benign Brain Tumor Cancer Registries

Amendment Act (Pub. L. No. 107-260) to include requirements for reporting brain-related tumors. Finally, section 803 of the Health Care Facilities Act (35 P.S. § 448.803) provides the Department with the authority to promulgate regulations relating to the licensure of health care facilities and allows the Department to require certain actions relating to disease control and prevention to occur with in health care facilities.

Background and Need for Amendments

The Department's regulations addressing communicable and noncommunicable diseases were first promulgated in 1959. The regulations were last significantly updated in 2001, which included updates to the list of reportable diseases, infections and conditions. The regulations were updated again in 2002 to add HIV to the list of reportable diseases, infections and conditions and again in 2020, to require reporting of all CD4 T-lymphocyte cell counts relating to HIV infection as well as viral load results and genotyping results. Comprehensive amendments to the regulations are needed to expand the list of reportable diseases, infections and conditions, to address changing standards and recommendations from experts, such as the CDC and the American Academy of Pediatrics (AAP), and to ensure the overall public health and safety by reducing the risk and spread of diseases, infections and conditions.

Over 400,000 health care practitioners, over 6,000 health care facilities, and 9,589 clinical laboratories will benefit from proposed amendments to reflect current terminology and enhance readability, such as the proposed alphabetical reporting charts in §§ 27.21a and 27.22 (relating to reporting of cases by health care practitioners and health care facilities; and reporting of cases by clinical laboratories). All 500 school districts, more than 160 brick-and-mortar charter schools, 14 cyber charter schools, approximately 396 colleges and universities, and 6,378 child care group settings, and students and employees, will also benefit from similar proposed

amendments to § 27.71a (relating to exclusion and readmission requirements for specific diseases, infections and conditions of food handlers, health care practitioners, schools, colleges and universities, child care group settings and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting). Children and staff in these settings will also benefit from amendments to readmission and exclusion requirements in proposed § 27.71a, to align with current recommendations from the AAP, which will ensure their health and safety by reducing the risk of exposure and becoming ill from certain diseases, conditions and infections.

The approximately 3,200 veterinarians will benefit from the Department's proposed amendments in § 27.24a (relating to reporting of cases by veterinarians) and § 27.35 (relating to reporting of cases of disease in animals) which will eliminate double reporting to the Department and to the Pennsylvania Department of Agriculture. The general public, consisting of approximately 13 million individuals in this Commonwealth, will also benefit from the proposed amendments to expand the list of reportable diseases, infections and conditions, and from amendments to clarify existing requirements, such as the disease control measures that the Department may take under § 27.60 (relating to disease control measures). These proposed amendments will protect public health by ensuring that the Department may act appropriately and quickly when needed, which will result in benefits such as preventing the spread of a disease, condition or infection.

The Department engaged with relevant stakeholders, potentially impacted agencies and local health departments in the spring and summer of 2024. Representatives from the following organizations participated in presentations and discussions held by the Department, in the summer of 2024, on proposed amendments to the regulations: the Children's Hospital of

Philadelphia, Pennsylvania Medical Society, the Hospital and Healthsystem Association of Pennsylvania, Pennsylvania Association of Community Health Centers, Philadelphia Department of Public Health, Erie County Department of Health, City of Philadelphia, PA Thrive Partnership Erie, LeadingAge PA, Pennsylvania State System of Higher Education, PA Association of School Administrators, Lehigh Valley Health Network, Montgomery County Department of Human Services, Doylestown Health, Doylestown Hospital, Main Line Health, Chester County Hospital, Hospital of the University of Pennsylvania, Jefferson Einstein Hospital, Pennsylvania Hospital, Patient Safety Authority, Jefferson Health System, and Temple Health Chestnut Hill Hospital. The Department met with local health departments on May 10, 2024, to discuss and present the proposed amendments to the regulations. The following local health departments participated in that discussion: Philadelphia Department of Public Health, Allegheny County Health Department, York City Health Bureau, Bucks County Department of Health, Delaware County Health Department, Montgomery County Health Department, Chester County Health Department, Bethlehem Health Bureau, Wilkes-Barre City Health Department, Allentown Bureau of Health, and Erie County Department of Health.

The Department reached out to sister agencies to discuss and present the proposed amendments to the regulations. On June 12, 2024, the Department met with the Pennsylvania Department of Education and the Pennsylvania Department of Human Services. On June 13, 2024, the Department met with the Pennsylvania Department of Environmental Protection, Pennsylvania Department of Drug and Alcohol Programs, Pennsylvania State Police, Pennsylvania Department of State, Pennsylvania Department of Conservation and Natural Resources, Pennsylvania Emergency Management Agency, and Pennsylvania Department of Agriculture. The Department also shared a final draft of the proposed amendments with these

agencies and the Pennsylvania Department of Aging in December 2025. The proposed amendments incorporate feedback received from relevant stakeholders, potentially impacted agencies and local health departments. Finally, the Department met with the Board for review and approval of the proposed amendments to the regulations in accordance with section 16(a) of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.16(a)). The Board approved the proposed amendments on July 17, 2025.

Description of Proposed Amendments

As a preliminary matter, the Department has included unchanged provisions throughout Chapter 27 in the annex for clarity and to assist the regulated community in its review of these proposed amendments. Unchanged definitions, subsections and sections, as well as proposed changes throughout Chapter 27 for gender neutrality and to conform to the *Pennsylvania Code and Bulletin Style Manual* (6th Edition, March 2025) exist in the annex but are not individually presented below.

Subchapter A. General Provisions

§ 27.1. Definitions.

ACIP

The Department proposes to delete the definition for ACIP as this term will no longer be used in the regulation.

AIDS

The Department proposes to replace the definition for "AIDS" with the following: "a late-stage HIV infection where the number of an individual's CD4 cells falls below 200 cells per cubic millimeter of blood, or an individual develops one or more opportunistic infections regardless of CD4 count." The Department proposes this amendment to align with the definition

of AIDS from HIV.gov, which is an organization spearheaded by the White House, the United States Department of Health and Human Services (DHHS) and several other Federal agencies. *See* HIV.gov. (2023). What are HIV and AIDS? Retrieved from https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids/.

Animal

The Department proposes to add a definition for "animal" for clarity. The proposed definition is intended to cover non-human organisms that can spread diseases. Zoonotic diseases are common diseases caused by harmful germs carried by animals that spread to people. CDC. (2024). About Zoonotic Diseases. Retrieved from https://www.cdc.gov/one-health/about/about-zoonotic-diseases.html. It is estimated that more than six out of ten known infectious diseases can be spread from animals to people and that three out of every four new or emerging infectious diseases in people come from animals. *Id*.

Assisted Living Residence

The Department proposes this definition to clarify the meaning of the word "assisted living residence" as it is used in the definition of "health care facility."

Birth Defects Registry

The Department anticipates the creation of an electronic platform for the reporting of birth defects and congenital anomalies, and proposes this definition to align with new, proposed requirements for the reporting of birth defects and congenital anomalies in § 27.37.

Brain-related tumor

The Department proposes this definition to align with the Benign Brain Tumor Cancer Registries Amendment Act (42 U.S.C. § 280e(a)(2)(B)) which defines the term "brain-related tumor" as "a listed primary tumor (whether malignant or benign) occurring in any of the

following sites: the brain, meninges, spinal cord, cauda equina, cranial nerve or any other part of the central nervous system, pituitary gland, pineal gland or craniopharyngeal duct." The term "listed" in the Brain Tumor Cancer Registries Act refers to "the International Classification of Diseases for Oncology (commonly referred to as the ICD-O)." The ICD-O is published by the World Health Organization (WHO) and is used in tumor or cancer registries for coding the site and histology of neoplasms, usually obtained from a pathology report. *See* World Health Organization. (2024). International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3). Retrieved from https://www.who.int/standards/classifications/other-classifications/international-classification-of-diseases-for-oncology.

CDC

The Department proposes to amend this definition to clarify that all references to the CDC in the proposed regulations are to the Centers of Disease Control and Prevention that are a part of the United States Department of Health and Human Services.

Case report form

The Department proposes to delete the definition of "case report form." This is an outdated term that will no longer be used in the regulations.

Central office

The Department proposes to delete the definition of "central office." This is an outdated term that will no longer be used in the regulation.

Child care group setting

The Department proposes to amend the definition of "child care group setting" to clarify that the term applies to premises in which care "in lieu of care by the parent or guardian for part of a 24-hour day" is provided to four or more children, unrelated to the operator. This proposed

amendment was requested by the Pennsylvania Department of Human Services' Office of Children, Youth and Families to clarify that the definition does not include group homes.

Close contact

The Department proposes to add a definition for "close contact" because identifying a person as possibly being infected with a disease or condition is part of contract tracing and disease prevention, where these individuals can expose others. The sufficient time and manner to possibly infect another will be different for each disease, infection or condition based on current recommendations and guidance from, for example, the CDC.

Commercial laboratory

The Department proposes to add this definition to aid the regulated community in determining which laboratories are required to comply with reporting requirements for select agents and toxins in new, proposed § 27.22a (relating to reporting of select agents or toxins). *See* Brokopp C., et al. (2006). "Laboratories." *Handbook of Biosurveillance*. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7150189.

Condition

The Department proposes, for clarity, to add a definition for "condition." The term "condition" is used in existing regulation and includes events or ailments that impact public health. Like infectious diseases, these events and ailments can be prevented through public health measures. Examples of "conditions" that impact public health include photokeratitis linked to light bulbs, chemical exposure from a train derailments, and lead, carbon monoxide and pesticide illnesses. *See* CDC. (2024). About Notifiable Non-Infectious Diseases and Conditions Data. Retrieved from https://www.cdc.gov/nndss/noninfectious-disease/about-data.html; Pennsylvania Department of Health, Bureau of Epidemiology, Division of Environmental Health

Epidemiology. (2023). Chemical Exposure and Health Outcomes of the East Palestine, Ohio Train Derailment on Pennsylvania First Responders. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/environmental-health/Report_Chemical%20Exposures%20and%20Health%20Outcomes%20-%20East%20Palestine%20Ohio.pdf; and CDC. (2024). Notifiable Non-Infectious Disease Data. Retrieved from https://www.cdc.gov/nndss/noninfectious-disease/index.html.

County morbidity reporting area

The Department proposes to delete the definition for "county morbidity reporting area." This term will no longer be used in the regulations as it refers to an outdated reporting system that is no longer in place.

Culture-independent diagnostic test

The Department proposes to add a definition for "culture-independent diagnostic test." The Department proposes to use this term throughout the regulations to refer to "a laboratory test that detects the presence of an antigen or nucleic acid associated with a specific pathogen, without growing the pathogen in a laboratory." This proposed definition aligns with the CDC's use of this term to describe this test, which is faster, easier, and lower cost than a standard "culture-based" test performed by a laboratory. *See* CDC. (2024). Foodborne Illness and Culture-Independent Diagnostic Tests. Retrieved from https://www.cdc.gov/foodnet/reports/cidt.html.

DHHS

The Department proposes to add a definition for "DHHS," the acronym for the United States Department of Health and Human Services. The Department proposes to add this

acronym for clarity when referencing this agency throughout the regulations, *e.g.*, in the definitions for "CDC," "public health emergency" and "select agent or toxin."

DOT—directly observed therapy

The Department proposes to define this term to align with the CDC's definition of "DOT" as the observance of a patient ingesting medication. DOT for tuberculosis treatment involves observing a patient ingest medication. DOT is typically conducted in person but can be done by video. Mangan, J., et al. (2023). "Recommendations for Use of Video Directly Observed Therapy During Tuberculosis Treatment – United States, 2023." *Morbidity and Mortality Weekly Report (MMWR)*, 72(12), 313-316. Retrieved from https://www.cdc.gov/mmwr/volumes/72/wr/mm7212a4.htm. The Department proposes to add "administration of a tuberculosis patient's injectable medication" to the definition to account for the observation of injectable medications that may be administered to a patient with tuberculosis, such as amikacin, kanamycin and capreomycin.

Emerging disease or condition

The Department proposes to add a definition for "emerging disease or condition" and to list this condition as reportable in § 27.21a. This proposed definition aligns with scholarly research on emerging diseases or conditions. *See*, *e.g.*, Wang, W., et. Al. (2021). "Emerging and Re-Emerging Diseases." *Pathogens*, 10(7): 827. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8308756/; Morens, D.M. and Fauci, A.S. (2013). "Emerging Infections Diseases: Threats to Human Health and Global Stability." *PLOS Pathogen*s. Retrieved from https://doi.org/10.1371/journal.ppat.1003467. Emerging diseases comprise a substantial fraction of all human infections and have resulted in some of the deadliest

pandemics in history, including the Black Death pandemic in the fourteenth century, the 1918 influenza pandemic, the HIV/AIDS pandemic, and most recently, the COVID-19 pandemic. *Id*.

FDA

The Department proposes to clarify that references to the FDA in the regulation are to the United States Food and Drug Administration.

Food

The Department proposes to add a definition for "food" to provide clarity regarding the provisions in this chapter related to foodborne illnesses, food poisoning, and food handlers. The Department proposes to adopt this definition from section 1-201.10(B) of the FDA's *2022 Food Code* to align with FDA standards for food safety. U.S. Food and Drug Administration. (2023). 2022 Food Code, 10th ed. Retrieved from https://www.fda.gov/media/164194/download?attachment. As described by the FDA, the Food Code "is a model for safeguarding public health" and "represents the FDA's best advice for a uniform system of provisions that address the safety and protection of food." FDA. (2023). 2022 Food Code. Retrieved from https://www.fda.gov/food/fda-food-code/food-code-2022.

Food handler

The Department proposes to add a definition for "food handler," a term that presently exists in this chapter and will continue to remain in the regulations, as proposed. The Department proposes to add this definition to provide clarity to the regulated community and has included examples of individuals the Department considers to be food handlers, to further aid the regulated community.

Food-contact surface

The Department proposes this definition to provide clarity to the regulated community regarding the instance of this term in the definition of "food handler." The Department proposes to adopt its definition of "food-contact surface" from FDA regulations at 21 CFR 110.3(g) (relating to definitions) with some modifications. The FDA defines "food-contact surfaces" as "those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations" and "includes utensils and food-contact surfaces of equipment." The Department is not aware of and could not find any published outbreaks associated with an ill food worker that only had contact with a food surface from which drainage onto food occurred. Thus, because of the targeted use of this term only in the definition of food handler, the Department proposes not to adopt language that references drainage onto food or onto surfaces that have direct contact with food.

HIV

The Department proposes to add a definition for "HIV," the acronym for "Human Immunodeficiency Virus" to clarify the use of the term in the existing and proposed regulations, and to align with the definition of HIV from HIV.gov, an organization spearheaded by the White House, DHHS and several other Federal agencies. HIV.gov. (2023). What are HIV and AIDS? Retrieved from https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids/.

Health care facility

The Department proposes deleting the words "chronic disease, or other type of" before the word "hospital" to clarify that the term "health care facility" encompasses all hospitals in this Commonwealth. The Department also proposes to add "an assisted living residence, a personal

care home" to make clear that the requirements in this chapter also apply to assisted living residences and personal care homes.

Hospital

The Department proposes this definition to clarify the meaning of the word "hospital" as it is used in the definition of "health care facility."

Immunization Information System

The Department proposes to add a definition for "immunization information system." This system is already in place, but the Department proposes to define the term in regulation for clarity and to align with the proposed addition of reporting requirements for immunization delivery in § 27.36.

Infectious agent

The Department proposes to amend the definition of "infectious agent" to cover the full range of pathogens that can cause disease (e.g. viruses, bacteria, fungi, parasites and prions), in recognition that not all infectious agents are organisms containing nucleic acids. *See*, *e.g.*, Barreto, M.L., et al. (2006). "Infectious diseases epidemiology." *Journal of Epidemiology & Community Health*, 60(3): 192-195. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2465549/ (recognizing that some proteins, known as prions, can be infectious).

LMRO

The Department proposes to delete the outdated definition for "LMRO." In practice, cases of diseases, infections or conditions are reported to either the Department or a local health department. The Department proposes to replace the term "LMRO" throughout the regulations in a manner that reflects current practices.

MDR—multidrug-resistant

The Department proposes to add the definition for MDR for clarity in the use of this term in the definition of "emerging disease or condition." The Department proposes to use the definition for MDR published by REVIVE, an outreach project launched by the Global Antibiotic Research & Development Partnership (GARDP). REVIVE. (2023). Multidrug-resistant (MDR). Retrieved from https://revive.gardp.org/resource/multidrug-resistant-mdr/. This definition was derived through a joint initiative between the CDC in the U.S. and the European Centre for Disease Prevention and Control. Magiorakos, A.-P., et al. (2011). "Multidrug-resistant, Extensively Drug-resistant and Pandrug-resistant Bacteria: An International Expert Proposal for Interim Standard Definitions for Acquired Resistance." *Clinical Microbiology and Infection*, 18(3), 268-281. Retrieved from https://onlinelibrary.wiley.com/doi/full/10.1111/j.1469-0691.2011.03570.x.

Mammal

The Department proposes to add this definition, derived from the encyclopedic definition of the term, but exclude humans, for clarity. *See* Brittanica. (2025). Mammal. Retrieved from https://www.britannica.com/animal/mammal.

Medical record

The Department proposes this amendment for consistency with other proposed amendments. The term "health care practitioner" is already defined in the regulations as "an individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board" and encompasses "physicians," "nurses" and "other health professionals."

Normally sterile body site

The Department proposes to use this term throughout the regulations and defines it here to provide clarity to the regulated community. The definition for this proposed term aligns with existing guidance from the Department, other states, and those who study infectious diseases. *See, e.g.,* Pennsylvania Department of Health. (2024). Normally Sterile Sites: Invasive Bacterial Diseases. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/programs/haip-as/_jcr_content/_cq_discarded/d8c15212-643b-4c1a-a836-b783ff3d0efd/Normally%20Sterile%20Sites.pdf; New Jersey Department of Health. (2023). Normally Sterile Sites: Invasive Bacterial Diseases. Retrieved from https://www.nj.gov/health/cd/documents/sterile_sites.pdf; and Miller, K.M., et al. (2022). "Standardization of Epidemiological Surveillance of Invasive Group A Streptococcal Infections." *Open Forum Infectious Diseases*, 9(Suppl 1): S31-S40. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9474937/.

Of public health significance

This proposed definition provides clarity for this term, which is used throughout the chapter. It is necessarily broad in order to encompass unforeseeable diseases, infections or conditions that could impact public health in the future. New York City's Health Code and Rules define the term "condition of public health interest" in a similar manner, as a "disease, illness, syndrome or injury, or other threat to health that is identifiable on an individual or community level and can reasonably be expected to lead to adverse health effects in the community." NYC. (2024). About DOH, Health Code and Rules, Article 11, Reportable Diseases, Conditions. Retrieved from https://www.nyc.gov/assets/doh/downloads/pdf/about/healthcode/health-code-article11.pdf.

Pandrug-resistant

The Department proposes to add this definition to align with the proposed addition of "pandrug-resistant organism infection" to the reporting requirements in §§ 27.21a and 27.22. The Department proposes to use the definition for pandrug-resistant published by REVIVE, an outreach project launched by the Global Antibiotic Research & Development Partnership (GARDP). REVIVE. (2023). Pandrug-resistant (PDR). Retrieved from https://revive.gardp.org/resource/pandrug-resistant/. This definition was derived through a joint initiative between the CDC in the U.S. and the European Centre for Disease Prevention and Control. Magiorakos, A.-P., et al. (2011). "Multidrug-resistant, Extensively Drug-resistant and Pandrug-resistant Bacteria: An International Expert Proposal for Interim Standard Definitions for Acquired Resistance." *Clinical Microbiology and Infection*, 18(3), 268-281. Retrieved from https://onlinelibrary.wiley.com/doi/full/10.1111/j.1469-0691.2011.03570.x.

Partner services

The Department proposes this definition to clarify the use of this term throughout the regulations. The Department proposes to align the definition for the term with the CDC. *See* CDC. (2021). Partner Services for HIV and STDs: A Guide for Health Care Providers. Retrieved from https://www.cdc.gov/stophivtogether/library/topics/treatment/brochures/cdc-hiv-lsht-treatment-brochure-partner-services-provider.pdf.

Perinatal exposure of a newborn to HIV

The Department proposes to update this definition to utilize current terminology.

Personal care home

The Department proposes this definition to clarify the meaning of the word "personal care home" as it is used in the definition of "health care facility."

Pesticide-related illness or injury

The Department proposes to adopt this definition from the CDC's surveillance case definition for "pesticide-related illness and injury, acute." The CDC's "surveillance case definition refers to any acute adverse health effect resulting from exposure to a pesticide product (defined under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA)) including health effects due to an unpleasant odor, injury from explosion of a product, inhalation of smoke from a burning product, and allergic reaction." CDC. (2021). Pesticide-related Illness and Injury, Acute 2010 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/pesticide-related-illness-and-injury-acute-2010/. As explained later in this preamble, the Department proposes to add "pesticide-related illness or injury, acute" as a reportable illness in § 27.21a(b) (relating to reporting of cases by health care practitioners and health care facilities).

Physician

The Department proposes to delete "physician" in favor of the more inclusive "health care practitioner." Other health care professionals, such as certified registered nurse practitioners, acting within the scope of their practice, may be involved in the diagnosis and treatment of patients with diseases, infections or conditions.

Public health emergency

The Department proposes this definition to align with the use of this term in the industry. *See*, *e.g.*, Nelson, C., et al. (2007). "Conceptualizing and Defining Public Health Emergency Preparedness." *American Journal of Public Health*, 97(Suppl 1): S9-S11. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1854988/. The Department proposes to add that the term includes public health emergencies as determined by the Governor of this

Commonwealth or the Secretary of DHHS to encompass the circumstances in which those two individuals may declare a public health emergency.

Quarantine

The Department proposes to amend this definition to replace the word "physician" with "health care practitioner acting within the scope of their practice" for consistency in the use of this term throughout the regulations, to include other practitioners, not just physicians, who may within the scope of their practice perform the same function, *e.g.*, determine that a person is noninfectious.

Reportable disease, infection or condition

The Department proposes to replace the cross-reference to "§ 27.2" with a broader cross-reference to "Subchapter B (relating to the reporting of diseases, infections and conditions)." This broader cross-reference is necessary to clarify that reporting requirements for diseases, infections or conditions are not limited to § 27.2, but are listed throughout Subchapter B, both currently and as proposed.

Research laboratory

The Department proposes this definition, consistent with the term as it is used in 28 Pa. Code § 5.82 (relating to research laboratories), to make clear which laboratories must report select agents or toxins under § 27.22a (relating to reporting of select agents or toxins).

School

The Department proposes to add this definition to clarify that the use of the term "school" in the proposed regulations includes those entities identified as "schools" by statute.

Select agent or toxin

The Department proposes to add this definition for clarity in the use of this term in the following sections: §§ 27.22(l), 27.22a, 27.201 and 27.202. The proposed definition aligns with the meaning of this term as used by the DHHS and the USDA, who have the authority to determine what is a select agent or toxin.

Student

The Department proposes to define this term for clarity to refer to persons in an educational setting or school community where the spread of infectious disease occurs and would impact others in the setting or community.

Surveillance; surveillance of disease

The Department proposes to add a definition for "surveillance" and to define this term as "the ongoing, systematic collection, analysis and interpretation of health-related data essential to planning, implementing and evaluation of public health practice." This proposed definition is intended to replace the term "surveillance of disease," which the Department proposes to delete.

Syndromic surveillance

The Department proposes to add this definition for consistency with the CDC. *See* Henning, K. J. (2004). "Overview of Syndromic Surveillance. What is Syndromic Surveillance?" *Morbidity and Mortality Weekly Report (MMWR)*, 53(Suppl); 5-11. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/su5301a3.htm.

Syndromic Surveillance System

The Department proposes to define this term for clarity and to align with the proposed addition of reporting requirements for hospital emergency department visit data for syndromic surveillance in proposed § 27.4a (relating to reporting hospital emergency department visit data for syndromic surveillance). This system is already in place.

Unusual occurrence

The Department proposes to add a definition for "unusual occurrence" to clarify the use of this term throughout the chapter. New diseases can be identified, such as Legionnaire's disease and hantavirus pulmonary syndrome, and known diseases may resurge, such as malaria and tuberculosis. *See* National Institute of Health. (2007). NIH Curriculum Supplement Series. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK20370/. Viruses also mutate over time, which may impact drug resistance, immune escape, vaccination, pathogenesis, and the emergence of new diseases. Sanjuan R. and Domingo-Calap, P. (2016). "Mechanisms of Viral Mutation." *Cell Mol Life Sci*, 2016 Jul 8;73(23):4433-4448. The definition of "unusual occurrence" is intended to cover a potential new disease, resurgence of a disease, or the mutation of a disease or condition that may impact public health.

USDA

The Department proposes to add a definition for "USDA," the acronym for the United States Department of Agriculture for clarity. The USDA is referenced in the definition of "select agency or toxin."

XDR

The Department proposes to add a definition for "XDR," adopted from REVIVE: Advancing Antimicrobial R&D and the Global Antibiotic Research & Development Partnership (GARDP). *See* REVIVE, GARDP. (2023). Extensively drug-resistant (XDR). Retrieved from https://revive.gardp.org/resource/extensively-drug-resistant-xdr/. This definition was derived through a joint initiative between the CDC in the U.S. and the European Centre for Disease Prevention and Control. *See* Magiorakos, A.-P., et al. (May 7, 2011). "Multidrug-resistant, Extensively Drug-resistant and Pandrug-resistant Bacteria: An International Expert Proposal for

Interim Standard Definitions for Acquired Resistance." *Clinical Microbiology and Infection*. Vol. 18, Issue 3, 268-281. Retrieved from https://onlinelibrary.wiley.com/doi/full/10.1111/j.1469-0691.2011.03570.x.

§ 27.3. Reporting outbreaks, unusual diseases, infections and conditions, and public health emergencies.

The Department proposes to add the words "public health emergencies" to the title to more accurately reflect the contents of this section. The Department also proposes to add headings to each of the subsections in this section for clarity and ease of readability.

Subsection (a)

The Department proposes to add "unless otherwise directed by the Department" to account for situations in which the Department may need to request that a person deviate from the reporting timeframes and mechanisms set forth in proposed paragraphs (1) and (2) of this subsection. The Department proposes to replace the phrase "within 24 hours, and in accordance with § 27.4 (relating to reporting cases)" with two new, proposed paragraphs. In paragraph (1), the Department proposes to require immediate reporting of an outbreak, by telephone, if the condition, infection or disease is one that requires immediate reporting under §§ 27.21a or 27.22. In paragraph (2), the Department proposes to require that all other outbreaks be reported by telephone within 24 hours. In general, a rapid response by the Department to control an outbreak of a condition, infection or disease will result in fewer persons being infected. The diseases, infections and conditions that require immediate reporting under proposed §§ 27.21a or 27.22 each pose unique risks to the public that may necessitate a rapid response from the Department in the event of an outbreak. This may include measures such as identifying and removing a contaminated food item, providing prophylactic treatment or vaccination to exposed persons, or

cohorting persons based on their sick of infection in an environment such as a nursing home. Each condition, infection, or disease that requires immediate reporting is specifically addressed under proposed §§ 27.21a or 27.22.

Subsection (b)

The Department proposes to add "unless otherwise directed by the Department" and to replace the phrase "within 24 hours, and in accordance with § 27.4" with "within 30 minutes, by telephone to the Department." Similar to an outbreak, a suspected public health emergency may necessitate a rapid response from the Department to protect public health. This may include measures such as identifying and removing a contaminated food item, providing prophylactic treatment or vaccination to exposed persons, or cohorting persons based on their sick of infection in an environment such as a nursing home.

Subsection (c)

The Department proposes to add "unless otherwise directed by the Department" and to replace the phrase "within 24 hours, and in accordance with § 27.4" with "within 30 minutes, by telephone to the Department." Similar to an outbreak or suspected public health emergency, an unusual or group expression of illness, which the Department has designated as a public health emergency, may necessitate a rapid response from the Department to protect public health. This may include measures such as identifying and removing a contaminated food item, providing prophylactic treatment or vaccination to exposed persons, or cohorting persons based on their risk of infection in an environment such as a nursing home.

§ 27.4a. Reporting hospital emergency data for syndromic surveillance.

This proposed section is new.

Subsection (a)

The Department proposes to require hospitals to report emergency department visit data to the Department. All hospitals in this Commonwealth are already voluntarily reporting this data to the Department through the Department's syndromic surveillance system. Therefore, there will be no impact on hospitals as a result of this proposed amendment. The Department proposes to add this reporting as a requirement in regulation to ensure that hospitals continue to report this data and that any future hospitals that open in this Commonwealth will report this data. The Department uses this data to detect unusual levels of illness or conditions to determine whether a response is needed. This data is used as an early warning system for detecting a matter of public health concern, such as a respiratory disease outbreak or injuries associated from a product.

Subsection (b)

The Department proposes a list of the data to be reported. The CDC conducts national syndromic surveillance through the National Syndromic Surveillance Program (NSSP). The data elements to be reported are the same as utilized by the NSSP, except for "other data elements deemed necessary by the Department." The Department proposes this addition to the data elements currently utilized by the NSSP, as new data elements may be needed for effective syndromic surveillance. Novel and emerging diseases are a concern and allowing new data elements to be added for syndromic surveillance will allow the Department, when necessary, to adapt to unforeseen circumstances.

Subsection (c)

The Department proposes that hospitals report emergency department visit data, in as near to real-time as possible but no later than 24 hours after presentation of the patient at the emergency department. The Department needs the data within this timeframe for early detection

of unusual levels of illness or conditions. Recent infectious disease threats, such as SARS, avian flu and pandemic influenza, have highlighted the need for governments and public health agencies to learn of potential infectious disease threats to facilitate timely and appropriate public health responses. *See* Paterson, B.J. and Durrheim, D.N. (2013). "The Remarkable Adaptability of Syndromic Surveillance to Meet Public Health Needs." *Journal of Epidemiology and Global Health*, 3:1, pp. 41-47. Retrieved from https://www.sciencedirect.com/science/article/pii/S2210600612000676.

Subsection (d)

The Department proposes to require hospitals to respond to Department inquiries regarding emergency department visit data within 24 hours. Reporting of certain emergency department visit data may require an immediate response from the Department, *e.g.*, when a patient is diagnosed with a communicable disease that poses a severe threat to human health, and the Department may need additional information from the hospital in those situations to take appropriate action. Additionally, data may be mistakenly reported, and clarification may be needed from the hospital to correct this data.

§ 27.4b. Additional reports.

This proposed section is new. The Department proposes to add language to require a person or entity required to report under this chapter to provide additional reports when circumstances warrant, *e.g.*, when something is incorrectly reported through the Department's electronic disease surveillance system.

§ 27.5a. Confidentiality of reports.

The Department proposes amendments to this section to align with sections 15 and 15.1 of the act (35 P.S. §§ 521.15 and 521.15a). The Department proposes to delete the word "case"

from the title of this section as the confidentiality provisions of this section are not limited to reports of cases received by the Department. The Department proposes to replace the words "case reports submitted to the Department or to an LMRO" with a cross-reference to section 15.1 to clarify that reports submitted under these regulations are confidential except as provided for by this section and by section 15.1 of the act. Section 15.1 of the act contains specific confidentiality provisions that apply only under a proclamation of disaster emergency in this Commonwealth. The Department also proposes to replace the words "LMRO" and "an LMRO" as noted above. In practice, cases are reported to either the Department or a local health department.

The Department proposes to also add in paragraph (1.1), an exception to permit disclosure where it is necessary to inform the public of the risk of a communicable disease, as determined by the Department or local health department, and when that disclosure would not violate another act or regulation. This proposed addition aligns with section 15(a)(2) of the act (35 P.S. § 521.15), which was added by Act 112 of 2020 and permits disclosure of reports and records of diseases to be disclosed where necessary to inform the public of the risk of a communicable disease. The Department proposes in paragraph (2) to add the word "Department" to the last sentence for consistency, and to clarify that this paragraph applies to both the Department and the local health department.

Subchapter B. Reporting of Diseases, Infections and Conditions

General

§ 27.21a. Reporting of cases by health care practitioners and health care facilities.

Subsection (a)

The Department proposes to rephrase the existing language for readability, to indicate that a health care practitioner or facility is required to report a case of a disease, infection or condition listed in proposed subsection (b), if the practitioner or facility diagnoses, treats or suspects because of symptoms or appearance, a person having that reportable disease, infection or condition, except in cases where a practitioner or facility has reported the case previously or where otherwise directed by this chapter or by the Department. These proposed amendments are reflected in paragraphs (1) and (1.1).

The Department proposes to delete existing paragraphs (2) through (5). Existing paragraph (2) indicates that a health care practitioner or health care facility is not required to report a case of influenza unless the disease is confirmed by laboratory evidence. The Department proposes, in subsection (b), to require reporting of influenza that is "confirmed by positive antigen or nucleic acid laboratory test, or point-of-care rapid test." Therefore, existing paragraph (2) will no longer be needed and could result in confusion if it were to remain.

Existing paragraph (3) indicates that a health care practitioner or health care facility is not required to report a case of chlamydia trachomatis infection unless the disease is confirmed by laboratory evidence of the infectious agent. The Department proposes, in subsection (b), to require reporting of chlamydia trachomatis, but to remove the need for laboratory testing before reporting, due to the development of more accurate point of care tests and related guidance from the CDC. *See* CDC. (2021). Chlamydial Infection Among Adolescents and Adults. Retrieved from https://www.cdc.gov/std/treatment-guidelines/chlamydia.htm. Therefore, existing paragraph (3) will no longer be needed and could result in confusion if it were to remain.

Existing paragraph (4) indicates that a health care practitioner or health care facility is not required to report a case of cancer unless the practitioner or facility provides screening, therapy

or diagnostic services to cancer patients. Cancer reporting requirements are addressed more specifically in existing § 27.31 (relating to reporting cases of cancer and brain-related tumors), which the Department proposes to amend, as explained in that section. Therefore, existing paragraph (4) will no longer be needed and could result in confusion if it were to remain.

Existing paragraph (5) indicates that only physicians and hospitals are required to report cases of AIDS. Reporting requirements for AIDS are addressed more specifically in existing § 27.32a(b) (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load results and HIV genotype test results, and perinatal exposure of newborns to HIV). Therefore, existing paragraph (5) is no longer needed and could result in confusion if it were to remain.

Subsection (b)

The Department proposes to replace the existing language in subsection (b) with new language and a new chart that lays out all diseases, infections and conditions, in alphabetical order, that are to be reported to the Department, along with the mechanism and timing for reporting.

The Department proposes to add language preceding the chart to indicate that "unless otherwise specified in this chapter or otherwise directed by the Department," a health care practitioner or health care facility shall follow the timeframes and manner of reporting set forth in the chart. The proposed addition of "unless otherwise specified in this chapter" accounts for requirements for diseases, infections and conditions that are covered elsewhere in the regulations, such as AIDS, HIV and diseases of the newborn. *See* § 27.32a and § 27.30 (relating to reporting cases of certain diseases in the newborn child).

The Department proposes the new chart format to make it easier for health care practitioners and health care facilities to locate specific reporting requirements by searching within the chart alphabetically to determine whether a disease, infection or condition needs to be reported, and on the same line, determine when and how to report the disease, infection or condition. The new chart contains proposed additions, as well as proposed updates to the existing reporting requirements. Below is a description and explanation of proposed amendments starting first with the diseases, infections and conditions currently listed in regulation, followed by those which will be new.

Subsection (b), paragraph (1)

Existing subsection (b)(1) requires the reporting of the following diseases, infections and conditions to the Department within 24 hours: Animal bites; Anthrax; Arboviruses; Botulism; Cholera; Diphtheria; Enterohemorrhagic E. coli.; Food poisoning outbreak; Haemophilus influenzae invasive disease; Hantavirus pulmonary syndrome; Hemorrhagic fever; Lead poisoning; Legionellosis; Measles (rubeola); Meningococcal invasive disease; Plague; Poliomyelitis; Rabies; Smallpox; and Typhoid fever. The Department proposes to delete existing subsection(b)(1) and to add the diseases, infections and conditions that are currently listed to the new chart, but with some exceptions and amendments, as described below.

Animal bites

The Department proposes not to add animal bites to the new chart and to instead place the reporting requirements for animal bites in new, proposed § 27.33b (relating to reporting cases of animal bites, scratches or contamination of open wounds or mucous membranes). Placing this requirement within its own section is appropriate as an animal bite is a particular type of wound that does not qualify as a disease, infection or condition.

Anthrax

Health care practitioners and health care facilities are already required to report cases of anthrax to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to require that cases of anthrax be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed anthrax as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Anthrax (*Bacillus anthracis*). Retrieved from https://ndc.services.cdc.gov/conditions/anthrax/. Anthrax is a deadly infection with *Bacillus anthracis*, a bacterium that the CDC classifies as a "Category A" agent alongside variola (smallpox), *Yersinia pestis* (plague), filoviruses (Ebola and Marburg viruses), and *Clostridium botulinum* toxin (botulism). CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp "Category A" agents pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*. Because of this risk, the Department proposes to require that cases of anthrax be reported immediately by telephone as well as within 24 hours to the Department's electronic disease surveillance system.

Arboviral infection (i.e., viral infections transmitted through the bite of an arthropod such as a mosquito or tick), not otherwise listed

Health care practitioners and health care facilities are already required to report cases of arbovirus to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to replace "arboviruses" with "arboviral infection (*i.e.*, viral

infections transmitted through the bite of an arthropod such as a mosquito or tick), not otherwise listed," and to create separate requirements within the chart for the arboviruses, such as yellow fever virus infection, West Nile virus and Zika virus, that pose the most significant risk to the public health. The Department proposes to retain the existing requirement that arboviral infections be reported within 24 hours to the Department's electronic disease surveillance system.

Botulism, excluding infant botulism and Botulism, infant

Health care practitioners and health care facilities are already required to report cases of botulism to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to create separate requirements for "botulism, excluding infant botulism" and "botulism, infant," due to the difference in botulinum antitoxin (BAT) that must be used for treatment and the unique public health response that is implemented for infant botulism.

The Department proposes to require that cases of "botulism, excluding infant botulism," be reported immediately by telephone and within 24 hours to the Department's electronic disease surveillance system, and to require that cases of infant botulism be reported within 24 hours to the Department's electronic disease surveillance system.

Non-infant botulism is a deadly bacterial infection that can be transmitted through contaminated food and some medical procedures, as well as through bioterrorism. CDC. (2024). About Botulism. Retrieved from https://www.cdc.gov/botulism/about/; CDC. (2019). Botulism: Bioterrorism. Retrieved from https://www.cdc.gov/botulism/bioterrorism/index.html. The CDC classifies botulism as a "Category A" disease alongside *Bacillus anthracis* (anthrax), variola (smallpox), *Yersinia pestis* (plague), filoviruses (Ebola and Marburg viruses), and *Clostridium*

botulinum toxin (botulism). CDC. (2018). Bioterrorism Agents/Diseases. CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp "Category A" agents pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*. Suspected infections must be reported as quickly as possible to the Department so that it may identify and prevent further spread from any source such as store-bought foods, homemade foods, medical offices and terrorism. CDC. (2024). About Botulism. Retrieved from https://www.cdc.gov/botulism/about/. The Department, therefore, proposes to require that cases be reported immediately by telephone as well as within 24 hours to the Department's electronic disease surveillance system.

The Department proposes to require that cases of "botulism, infant" be reported, within 24 hours, to the Department's electronic disease surveillance system. Infant botulism can be acquired from the environment, as well as from specific foods that would not normally cause disease in adults, such as honey. World Health Organization. (2018). Botulism. Retrieved from https://www.who.int/news-room/fact-sheets/detail/botulism. The treatment for infant botulism is also unique, as providers use a reduced dose of the adult BAT known as "human-origin anti-A, anti-B botulinum antitoxin (BabyBIG)." The CDC has designated the Infant Botulism Treatment and Prevention Program at the California Department of Public Health as the sole storage and processing site for BabyBIG, which providers are directed to contact immediately upon suspicion of infant botulism and to not wait for laboratory confirmation. CDC. (2024). Clinical Overview of Infant Botulism. Retrieved from

https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html. Providers are directed to contact their state health department, after contacting the Botulism Treatment and Prevention Program. *Id*. The Department has therefore determined that reporting, within 24 hours, is appropriate to avoid any possible delay in obtaining treatment.

Cholera

Health care practitioners and health care facilities are already required to report cases of cholera to the Department, within 24 hours, under existing subsection (b)(1). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add cholera to the new chart with no amendments to the existing method or timeframe for reporting.

Diphtheria

Health care practitioners and health care facilities are already required to report cases of diphtheria to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of diphtheria be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed diphtheria as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Diphtheria. Retrieved from https://ndc.services.cdc.gov/conditions/diphtheria/. Before the development of vaccines, diphtheria was one of the most common causes of illness and death in children in the United States. CDC. (2025). Manual for the Surveillance of Vaccine-Preventable Diseases, Chapter 1: Diphtheria. Retrieved from https://www.cdc.gov/surv-manual/php/table-of-contents/chapter-1-diphtheria.html. Although cases in the United States are now rare due to widespread vaccination, diphtheria is still prevalent in countries with low routine immunization coverage, and travel to an

endemic region continues to be a cause of diphtheria cases in the United States. *Id*. An outbreak of diphtheria in the 1990's in the former Soviet Union, where diphtheria was believed to be well controlled, highlights the need for continued vigilance of this deadly disease. *Id*. The Department therefore proposes to require reporting of diphtheria immediately by telephone, with follow-up to the Department's electronic disease surveillance system within 24 hours.

Enterohemorrhagic E. coli

Health care practitioners and health care facilities are already required to report cases of enterohemorrhagic *E. coli* to the Department, within 24 hours, under existing subsection (b)(1). This reporting is done through the Department's electronic disease surveillance system. The Department proposes in the new chart to replace "enterohemorrhagic *E. coli*" with "Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC) infection." While the terms are interchangeable, STEC is the more commonly used and recognized term for the subset of *E. coli* bacteria that produce Shiga toxin. *See* CDC. (2024). About Escherichia coli Infection. Retrieved from https://www.cdc.gov/ecoli/about/. The Department does not propose any amendments to the manner and timeframe that is currently required for reporting STEC.

Food poisoning outbreak

Health care practitioners and health care facilities are already required to report outbreaks of food poisoning to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to replace "food poisoning outbreak" with "gastrointestinal illness outbreak," as this is the more appropriate term for bacterial, viral, or parasitic infections, such as *Salmonella* or Noroviruses, that can be transmitted via contaminated food, water or other beverages, animals, animal products and infected people. *See*, *e.g.*, North Carolina Department of Health and Human Services (2020). Food Poisoning & Food-Borne

Illness. Retrieved from https://epi.dph.ncdhhs.gov/cd/diseases/food.html and North Dakota Health & Human Services (2022). Foodborne and Gastrointestinal illnesses. Retrieved from https://www.hhs.nd.gov/health/diseases-conditions-and-immunization/foodborne-and-gastrointestinal-illness. The Department proposes to require reporting of gastrointestinal illness outbreak by telephone, as the Department's electronic disease surveillance system only supports reporting individual cases, not outbreaks. Thus, the most efficient and effective way for a health care provider or facility to report a surge of cases is by telephone.

The Department proposes to carve out separate reporting requirements for pathogen-produced toxins that cause gastrointestinal illnesses in the new chart with a requirement for the reporting of "foodborne illness due to toxins (including mushroom toxins, ciguatera toxins, scombrotoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, staphylococcus enterotoxin, *Bacillus cereus* toxin, and others." The Department proposes to require that these illnesses be reported immediately by telephone and within 24 hours by electronic disease surveillance system. Foodborne toxins can cause a large variety of illnesses, and accordingly variable symptoms, from typically moderate reactions to toxins such as Scombrotoxin and Agricola, to fatal reactions to highly deadly toxins such as paralytic shellfish toxins, Protoplasmic poison, and Tetrodotoxin that can cause death "in a matter of hours." Abraham, A., et al. (2012). *Foodborne Pathogenic Microorganisms and Natural Toxins*. Bad Bug Book: Food and Drug Administration. Retrieved from https://www.fda.gov/media/83271/download. Often, cooking or preparing the fish, shellfish, mushrooms or other types of food that can harbor these toxins does not destroy the toxin, making prompt identification and removal of the source vital to protect other individuals from harm. *Id*.

As recently as 2022, an outbreak of foodborne illness related to mushroom-related poisonings occurred in this Commonwealth, with thirteen cases in the span of one month. Pennsylvania Department of Health. (2022). Increased Reports of Mushroom Poisoning Following Consumption of Foraged Mushrooms. Retrieved from https://www.health.pa.gov/topics/Documents/HAN/2022-675-11-18-ADV-Mushroom.pdf. In one case, the individual required a liver transplant, and in another case, the individual died. Due to the potential for severe disease associated with many foodborne toxins, the Department proposes reporting immediately by telephone, followed by reporting within 24 hours to the Department's electronic disease surveillance system.

Haemophilus influenzae invasive disease

Health care practitioners and health care facilities are already required to report *Haemophilus influenzae* invasive disease to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to add *Haemophilus influenzae* invasive disease to the new chart with no amendments to the existing method or timeframe for reporting.

Hantavirus pulmonary syndrome

Health care practitioners and health care facilities are already required to report cases of hantavirus pulmonary syndrome (HPS) to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of HPS be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

HPS is a deadly respiratory condition caused by hantaviruses that are transmitted to humans by rodents. HPS in the United States is not currently human-to-human transmissible. Individuals contract HPS through contact with an infected rodent's saliva, urine or droppings.

CDC. (2024). About Hantavirus. Retrieved from https://www.cdc.gov/hantavirus/about/index.html. HPS has a mortality rate of 36%. CDC. (2021). Hantavirus Pulmonary Syndrome (HPS) - 2015 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/hantavirus-pulmonary-syndrome-2015/.

There are no specific treatments for HPS outside of supportive care. However, "if infected individuals are recognized early and receive medical care in an intensive care unit, they may do better. In intensive care, patients are intubated and given oxygen therapy to help them through the period of severe respiratory distress." CDC. (2024). About Hantavirus. Retrieved from https://www.cdc.gov/hantavirus/about/index.html. To decontaminate sources of infection, either at homes or places of work, and thereby prevent additional exposures, the Department must receive immediate notification of any identified HPS cases. The Department therefore proposes immediate reporting by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

Hemorrhagic fever

Health care practitioners and health care facilities are already required to report cases of hemorrhagic fever to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to replace "hemorrhagic fever" with "hemorrhagic fever, viral, not otherwise listed," and to separately list specific diseases causing this condition that pose a significant risk to the public health, such as Ebola, Marburg and arenaviruses. The Department proposes to require that cases of "hemorrhagic fever, viral, not otherwise listed" be reported immediately by telephone and within 24 hours to the Department's electronic disease surveillance system.

Viral hemorrhagic fevers are caused by several ribonucleic acid (RNA) viruses, including arenaviruses, bunyavirales, filoviruses and flaviviruses. Some viral hemorrhagic fevers cause mild illness, while others cause severe, life-threatening illnesses that impact many organ systems of the body damage the overall cardiovascular system and reduce the body's ability to function on its own. CDC. (2024). About Viral Hemorrhagic Fevers. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/about/. Individuals with suspected or confirmed viral hemorrhagic fever should remain in isolation until it is determined that they do not have viral hemorrhagic fever, or they are no longer infectious. CDC. (2024). Viral Hemorrhagic Fevers (VHFs) – Public Health Management of People with Suspected or Confirmed VHF or High-Risk Exposures. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/php/public-health-strategy/people-with-suspected-or-confirmed-vhf-or-high-risk.html. In addition, certain viral hemorrhagic fevers, including filoviruses and arenaviruses, are classified as "Category A" agents alongside *Bacillus anthracis* (anthrax), variola major (smallpox), *Yersinia pestis* (plague) and *Clostridium botulinum* toxin (botulism). CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. Any outbreaks of these diseases would thus be considered a risk to national security. *Id*. Due to this risk and the need to isolate individuals who have the disease, the Department proposes to require immediate notification of viral hemorrhagic fevers, with follow-up to the Department's electronic disease surveillance system within 24 hours, so that isolation and other preventative measures can be implemented prior to an outbreak of this unpredictable and predominantly untreatable condition. CDC. (2024). About Viral Hemorrhagic Fevers. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/about/.

Lead poisoning

Health care practitioners and health care facilities are already required to report cases of lead poisoning to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to replace "lead poisoning" with "lead results for persons of all ages, including negative results or results below the limit of detection, from venous or capillary blood specimens." The Department proposes to require reporting of lead test results through the Department's electronic disease surveillance system "within 24 hours" consistent with the existing requirement for reporting of lead poisoning within 24 hours.

The Department proposes the expansion of the existing requirement to all lead results to identify remaining at-risk geographic areas, identify prioritization of limited resources, identify emerging sources of exposure and inform strategic plans to remove or reduce sources, and to target provider education efforts. *See* CDC. (2024). Data and Statistics. Retrieved from https://www.cdc.gov/lead-prevention/php/data/index.html. Undetected and untreated lead poisoning can cause severe impairments, including mood disorders, memory and concentration problems, seizures, renal failure, miscarriages and stillbirths in pregnant individuals and death, while children can additionally exhibit "reduced postnatal growth, decreased IQ, and inattention and behavior problems." Mayo Clinic. (2022). Lead Poisoning. Retrieved from https://www.mayoclinic.org/diseases-conditions/lead-poisoning/symptoms-causes/syc-20354717. Mandating reporting of every individual who seeks a lead blood test, as opposed to the current minimum blood level reporting requirement, will allow the Department to identify, inform and re-test individuals with potentially false-negative lead poisoning results from further exposure.

Legionellosis

Health care practitioners and health care facilities are already required to report cases of legionellosis to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to replace "legionellosis" with "legionellosis, including Pontiac fever."

The Department proposes the addition of "Pontiac fever" to clarify that this milder form of infection with *Legionella* bacteria must also be reported to the Department, as it is indicative of *Legionella* growth and risk of a potential outbreak, which would necessitate removing *Legionella* from the water identified as the source of infection. CDC. (2024). About Pontiac Fever. Retrieved from https://www.cdc.gov/legionella/about/about-pontiac-fever.html#cdc_disease_basics_risk-risk-factors. Legionnaires' disease, which is also caused by *Legionella*, is a severe and sometimes fatal respiratory infection that presents heightened risks for hospitalized patients. About one out of every ten people who get sick with Legionnaires' disease will die due to complications; this increases to about one out of every four who get sick with Legionnaires' while in a health care facility. CDC. (2024). About Legionnaires' Disease. Retrieved from https://www.cdc.gov/legionella/about/. The CDC has designated legionellosis as a nationally notifiable disease since 1974. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) - Legionellosis. Retrieved from https://ndc.services.cdc.gov/conditions/legionellosis/.

The Department must be informed of *Legionella* contaminations as quickly so that infected water systems can be identified and decontaminated and so that other countermeasures can be implemented to protect people from exposure, especially in health care settings where the risk of death from Legionnaires' disease is highest. The Department proposes to require that

cases of legionellosis, including Pontiac fever be reported within 24 hours, to the Department's electronic disease surveillance system.

Measles (rubeola)

Health care practitioners and health care facilities are already required to report cases of measles (rubeola) to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of measles be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed measles as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Measles / Rubeola. Retrieved from https://ndc.services.cdc.gov/conditions/measles/. Although the United States has maintained measles elimination status for almost twenty years, measles outbreaks continue to occur around the world, and importation of measles cases continues. CDC. (2024). History of Measles. Retrieved from https://www.cdc.gov/measles/about/history.html. Measles is highly contagious and can lead to serious complications, including hospitalization, pneumonia, encephalitis or death. CDC. (2024). Measles Symptoms and Complications. Retrieved from https://www.cdc.gov/measles/signs-symptoms/. As of May 15, 2025, a total of 1,024 confirmed measles cases were reported by 31 jurisdictions: Alaska, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, New Jersey, New Mexico, New York City, New York State, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia and Washington. CDC. (2025). Measles Cases and Outbreaks. Retrieved from https://www.cdc.gov/measles/data-research/. The ability of measles to spread quickly and the danger it presents make rapid implementation of isolation and quarantine measures vital to the

prevention of outbreaks. The Department therefore proposes immediate reporting by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

Meningococcal invasive disease

Health care practitioners and health care facilities are already required to report cases of meningococcal invasive disease to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes, in the new chart, to replace "meningococcal invasive disease" with "*Neisseria meningitis* (meningococcus) invasive disease, including meningococcal meningitis," to clarify which etiologic agent must be reported and expand the scope of reporting to include cases of meningitis caused by the same pathogen. The Department proposes to require that cases of *Neisseria meningitis* (meningococcus) invasive disease, including meningococcal meningitis, be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed meningococcal disease as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Meningococcal Disease. Retrieved from https://ndc.services.cdc.gov/conditions/meningococcal-disease/. Meningococcal disease is a deadly infection caused by the bacteria *Neisseria meningitidis* that can be spread person-to-person through saliva. CDC. (2022). Meningococcal Disease - Causes and How It Spreads. Retrieved from https://www.cdc.gov/meningococcal/about/causes-transmission.html. Meningitis and blood stream infections caused by these bacteria "can be deadly in a matter of hours" and cause long-term disability in about one out of five of those who do survive. CDC. (Feb. 7, 2022). Meningococcal Disease - Diagnosis, Treatment, and Complications. Retrieved from https://www.cdc.gov/meningococcal/about/diagnosis-treatment.html. Even with antibiotics, around ten to fifteen out of 100 people with

meningococcal disease will die. *Id*. The CDC therefore recommends providers begin antibiotic treatment even if the infection is only suspected. *Id*.

Outbreaks of meningococcal disease have occurred in the United States as recently as 2023. CDC. (2025). Meningococcal Disease Surveillance and Trends. Retrieved from https://www.cdc.gov/meningococcal/php/surveillance/index.html. It is critical that the Department be notified immediately of any *Neisseria meningitidis* infection in this Commonwealth, so that it may provide guidance for treatment, implement isolation measures, and begin contact tracing to prevent outbreaks of this potentially fatal disease. The Department therefore proposes immediate reporting of outbreak cases by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

Plague

Health care practitioners and health care facilities are already required to report cases of plague to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of plague be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed plague as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) - Plague. Retrieved from https://ndc.services.cdc.gov/conditions/plague/. Plague stems from an infection from *Yersinia pestis*, a bacterium that the CDC classifies as a "Category A" agent alongside *Bacillus anthracis* (anthrax), variola major (smallpox), *Bacillus anthracis* (anthrax), filoviruses (Ebola and Marburg viruses) and *Clostridium botulinum* toxin (botulism). CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category A" agents pose a risk to

national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*. Several cases of pneumonic plague in an area would constitute a public health emergency, requiring an immediate response from public health authorities. Additionally, any case of plague outside areas where plague naturally occurs or in people with no history of travel would be a cause for concern. CDC. (2024). Bioterrorism and Plague: Preparedness. Retrieved from https://www.cdc.gov/plague/bioterrorism/index.html.

It is critical that the Department be notified immediately of any case of plague in this Commonwealth, so that an investigation can begin as soon as possible to determine the source of the infection and how it was acquired. The Department therefore proposes immediate reporting by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

Poliomyelitis and Poliovirus infection, nonparalytic

Health care practitioners and health care facilities are already required to report cases of poliomyelitis to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of poliomyelitis be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system. The Department also proposes to add "poliovirus infection, nonparalytic" to the new chart.

The CDC has listed paralytic polio as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Poliomyelitis, Paralytic. Retrieved from https://ndc.services.cdc.gov/conditions/poliomyelitis-paralytic/. Poliomyelitis (polio) is a debilitating infection with poliovirus that can cause meningitis and disabling or

deadly paralysis. CDC. (2024). About Polio in the United States. Retrieved from https://www.cdc.gov/polio/about/. There is no cure or specific treatment for polio. *Id*. The United States experienced its first case of paralytic poliomyelitis in over ten years in 2022, showing that the disease still poses a threat to those who are not vaccinated against the disease. Anushree, R. et al. (2022). "Polio Returns to the USA: An Epidemiological Alert." *Annals of Medicine & Surgery (Lond)*, 82: 104563. Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC9577438/.

The CDC has classified paralytic polio as "immediately notifiable, extremely urgent," which means state and local health departments are required to report cases to the CDC within 4 hours. CDC. (2024). Reporting Suspected Cases. Retrieved from https://www.cdc.gov/polio/php/case-reporting/. The immense danger posed by a recurrence of poliomyelitis in the United States, as well as CDC requirements, necessitate immediate reporting of any cases of poliomyelitis to the Department. The Department therefore proposes immediate reporting of cases by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

As noted, the Department also proposes to add "poliovirus infection, nonparalytic" to the new chart. Nonparalytic poliovirus refers to an individual who has polio but does not have symptoms of paralytic poliomyelitis. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) - Poliovirus Infection, Nonparalytic 2010 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/poliovirus-infection-nonparalytic-2010/. The CDC has listed poliovirus infection, nonparalytic, as a nationally notifiable disease since 2007. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Poliovirus Infection, Nonparalytic. Retrieved from https://ndc.services.cdc.gov/conditions/poliovirus-infection-

nonparalytic/. The CDC has classified nonparalytic polio as "immediately notifiable, urgent," which means state and local health departments are required to report cases to the CDC within 24 hours. CDC. (2024). Reporting Suspected Cases. Retrieved from https://www.cdc.gov/polio/php/case-reporting/. The Department proposes to require reporting of nonparalytic poliovirus to the Department immediately by telephone and to the Department's electronic disease surveillance system within 24 hours to align with CDC's requirements.

Rabies

Health care practitioners and health care facilities are already required to report cases of rabies to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of rabies be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system. The Department also proposes to replace "rabies" with "rabies, human" to clarify that only cases of rabies in humans, not animals, are required to be reported to the Department.

Rabies virus infections in humans, without vaccine administration prior to the appearance of symptoms, invariably leads to death. Cleveland Clinic. (2022). Rabies. Retrieved from https://my.clevelandclinic.org/health/diseases/13848-rabies. Cases of human rabies infections in the United States are predominantly spread through bats that leave small bite marks, making detection of the virus before the individual becomes symptomatic unlikely. *Id*. Given the near 100% mortality rate for symptomatic rabies infections, the Department must be informed as soon as possible of any newly identified cases to prevent any spread of the disease, and to identify existing infection before an individual develops symptoms. The Department therefore proposes immediate reporting by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

Smallpox

Health care practitioners and health care facilities are already required to report cases of smallpox to the Department, within 24 hours, under existing subsection (b)(1). The Department proposes to require that cases of smallpox be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

Smallpox has been eradicated through vaccination. CDC. (2016). What is Smallpox? Retrieved from https://www.cdc.gov/smallpox/about/index.html. However, the CDC still classifies smallpox as a "Category A" agent alongside *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), filoviruses (Ebola and Marburg viruses), and *Clostridium botulinum* toxin (botulism). CDC (Apr. 4, 2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category A" agents pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*.

Additionally, the United States ceased smallpox vaccination after its eradication, meaning few people have any immunity to this disease; however, no treatment has proven effective. CDC. (2022). Treatment of Smallpox. Retrieved from https://www.cdc.gov/smallpox/treatment/. While in the past, most people with smallpox recovered, about three out of every ten who contracted the disease died. CDC. (2016). What is Smallpox? Retrieved from https://www.cdc.gov/smallpox/about/index.html. Those who survived were left with permanent scars over large areas of their body, including their face, and some developed blindness from the disease. *Id*. If an outbreak of smallpox were to occur,

vaccinations would be needed to control it. *Id*. As such, it is imperative that the Department be notified immediately of any cases to take appropriate measures. The Department therefore proposes immediate reporting by telephone, with follow-up to the electronic disease surveillance system within 24 hours.

Typhoid fever

Health care practitioners and health care facilities are already required to report cases of typhoid fever to the Department, within 24 hours, under existing subsection (b)(1). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add typhoid fever to the new chart with no amendments to the existing method or timeframe for reporting.

Subsection (b), paragraph (2)

Existing subsection (b)(2) requires the reporting of the following diseases, infections and conditions to the Department within 5 work days: AIDS; Amebiasis; Brucellosis; CD4 T-lymphocyte counts and percentages; Campylobacteriosis; Cancer; Chancroid; Chickenpox (Varicella); Chlamydia trachomatis infections; Congenital adrenal hyperplasia (CAH) in children under 5 years of age; Creutzfeldt-Jakob Disease; Cryptosporidiosis; Encephalitis; Galactosemia in children under 5 years of age; Giardiasis; Gonococcal infections; Granuloma inguinale; Guillain-Barre syndrome; HIV; HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results; Hepatitis, viral, acute and chronic cases; Histoplasmosis; Influenza; Leprosy (Hansen's disease); Leptospirosis; Listeriosis; Lyme disease; Lymphogranuloma venereum; Malaria; Maple syrup urine disease (MSUD) in children under 5 years of age; Meningitis (all types not caused by invasive Haemophilus influenza or Neisseria meningitis); Mumps; Perinatal exposure of a newborn to HIV; Pertussis (whooping

cough); Phenylketonuria (PKU) in children under 5 years of age; Primary congenital hypothyroidism in children under 5 years of age; Psittacosis (ornithosis); Rickettsial diseases; Rubella (German measles) and congenital rubella syndrome; Salmonellosis; Shigellosis; Sickle cell disease in children under 5 years of age; Staphylococcus aureus, Vancomycin-resistant (or intermediate) invasive disease; Streptococcal invasive disease (group A); Streptococcus pneumoniae, drug-resistant invasive disease; Syphilis (all stages); Tetanus; Toxic shock syndrome; Toxoplasmosis; Trichinosis; Tuberculosis, suspected or confirmed active disease (all sites); and Tularemia. The Department proposes to delete existing subsection(b)(2) and to add the diseases, infections and conditions that are currently listed to the new chart, but with some exceptions and amendments, as described below.

AIDS

The Department proposes not to add AIDS to the new chart. Specific reporting requirements for AIDS exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of AIDS are in existing § 27.32a, it is not necessary to include them again in the new chart.

Amebiasis

Health care practitioners and health care facilities are already required to report cases of amebiasis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add amebiasis to the new chart with no amendments to the existing method or timeframe for reporting.

Brucellosis

Health care practitioners and health care facilities are already required to report cases of brucellosis to the Department, within 5 work days, under existing subsection (b)(2). The Department proposes to require that cases of brucellosis be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed brucellosis as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Brucellosis. Retrieved from https://ndc.services.cdc.gov/conditions/brucellosis/. Brucellosis, a bacterial infection, is contracted through the consumption of raw or unpasteurized dairy products, contact with infected animals, or inhalation, and can cause fevers, arthritis, chronic fatigue, depression, endocarditis, and varied neurological symptoms long after treatment is completed. Mayo Clinic (2021). Brucellosis. Retrieved from https://www.mayoclinic.org/diseases-conditions/brucellosis/symptoms-causes/syc-20351738; CDC. (2024). About Brucellosis. Retrieved from https://www.cdc.gov/brucellosis/about/. Brucella species, the etiologic agent that causes brucellosis is classified as a "Category B" agent. CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category B" agents are moderately easy to disseminate, result in moderate morbidity rates and low mortality rates, and require enhanced disease surveillance. *Id*.

Because of the potential for Brucella to be used as a biological weapon, the Department proposes to require that cases of brucellosis be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system, so that appropriate measures can be taken to protect public health and safety.

CD4 T-lymphocyte counts and percentages

The Department proposes not to add CD4 T-lymphocyte counts and percentages to the new chart. Specific reporting requirements for CD4 T-lymphocyte counts and percentages exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of CD4 T-lymphocyte counts and percentages are in existing § 27.32a, it is not necessary to include them again in the new chart.

Campylobacteriosis

Health care practitioners and health care facilities are already required to report cases of campylobacteriosis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add campylobacteriosis to the new chart with no amendments to the existing method or timeframe for reporting.

Cancer

The Department proposes not to add cancer to the new chart. Specific reporting requirements for cancer exist currently in § 27.31 (reporting cases of cancer and brain-related tumors). Proposed amendments are described within that section. Because requirements for the reporting of cancer are in § 27.31, it is not necessary to include them again in the new chart.

Chancroid

Health care practitioners and health care facilities are already required to report cases of chancroid to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add chancroid to the new chart with no amendments to the existing method or timeframe for reporting.

Chickenpox (varicella)

Health care practitioners and health care facilities are already required to report chickenpox (varicella) to the Department, within 5 work days, under existing subsection (b)(2). The Department proposes to include "chickenpox" in the new chart, but to rename it to "*Varicella* infection (chickenpox), excluding shingles," to clarify that initial infections with the varicella-zoster virus must be reported but latent infections (*i.e.*, shingles) do not. The CDC has identified chickenpox, but not shingles, as a nationally notifiable disease. *See* CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Varicella / Chickenpox. Retrieved from https://ndc.services.cdc.gov/conditions/varicella/. Additionally, shingles, which occurs when the virus that causes chickenpox reactivates in the body of someone who has already had chickenpox, is only contagious to someone who has not had chickenpox or who has not been vaccinated against chickenpox. CDC. (2025). About Shingles (Herpes Zoster). Retrieved from https://www.cdc.gov/shingles/about/index.html. The Department proposes to add chickenpox to the new chart with no amendments to the existing method or timeframe for reporting.

Chlamydia trachomatis infections

Health care practitioners and health care facilities are already required to report cases of chlamydia trachomatis infections to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add chlamydia trachomatis infections to the new chart with no amendments to the existing method or timeframe for reporting.

Congenital adrenal hyperplasia (CAH) in children under 5 years of age

The Department proposes not to add "congenital adrenal hyperplasia (CAH) in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will

be addressed in proposed § 27.30 (relating to reporting cases of certain diseases in the newborn child), described below.

Creutzfeldt-Jakob Disease

Health care practitioners and health care facilities are already required to report cases of Creutzfeldt-Jakob disease to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add Creutzfeldt-Jakob disease to the new chart with no amendments to the existing method or timeframe for reporting.

Cryptosporidiosis

Health care practitioners and health care facilities are already required to report cases of cryptosporidiosis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add cryptosporidiosis to the new chart with no amendments to the existing method or timeframe for reporting.

Encephalitis

Health care practitioners and health care facilities are already required to report cases of encephalitis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add encephalitis to the new chart with no amendments to the existing method or timeframe for reporting.

Galactosemia in children under 5 years of age

The Department proposes not to add "galactosemia in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in

proposed § 27.30 (relating to reporting cases of certain diseases in the newborn child), described below.

Giardiasis

Health care practitioners and health care facilities are already required to report cases of giardiasis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add giardiasis to the new chart with no amendments to the existing method or timeframe for reporting.

Gonococcal infection

Health care practitioners and health care facilities are already required to report cases of gonococcal infections to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add gonococcal infections to the new chart with no amendments to the existing method or timeframe for reporting.

Granuloma inguinale

Health care practitioners and health care facilities are already required to report cases of granuloma inguinale to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add granuloma inguinale to the new chart with no amendments to the existing method or timeframe for reporting.

Guillain-Barre syndrome

Health care practitioners and health care facilities are already required to report cases of Guillain-Barre syndrome to the Department, within 5 work days, under existing subsection

(b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add Guillain-Barre syndrome to the new chart with no amendments to the existing method or timeframe for reporting.

HIV

The Department proposes not to add HIV to the new chart. Specific reporting requirements for HIV exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of HIV are in existing § 27.32a, it is not necessary to include them again in the new chart.

HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results

The Department proposes not to add HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results to the new chart. Specific reporting requirements for these results exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of these test results are in existing § 27.32a, it is not necessary to include them again in the new chart.

Hepatitis, viral, acute and chronic cases

The Department proposes to add hepatitis to the new chart, but to separate reporting requirements for hepatitis by type, as follows: hepatitis A, acute; hepatitis B, acute; hepatitis B, chronic; hepatitis B, perinatal; hepatitis C, acute; hepatitis C, chronic; hepatitis C, perinatal; hepatitis D, acute; hepatitis D, chronic; hepatitis E, acute; hepatitis E, chronic; and hepatitis, viral, other types.

Health care practitioners and health care facilities are already required to report acute cases of hepatitis to the Department, within 5 work days, under existing subsection (b)(2). The

Department proposes to require that acute cases of hepatitis A and hepatitis B be reported within 24 hours, and other acute cases to be reported within 5 work days.

The CDC has listed hepatitis A, acute, as a nationally notifiable disease since 1966. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis A, Acute. Retrieved from https://ndc.services.cdc.gov/conditions/hepatitis-a-acute/. Hepatitis A is a highly infectious, short-term liver disease that only presents acutely. CDC. (2025). Hepatitis A Basics. Retrieved from https://www.cdc.gov/hepatitis-a/about/index.html. In 1995, a vaccine was developed that significantly reduced total case numbers of this viral disease. However, in recent years, the number of infections has increased due to multiple outbreaks of hepatitis A resulting from person-to-person contact, particularly among those who use drugs, those who are homeless and men who have sex with men. *Id.* This Commonwealth has been in "outbreak" status for hepatitis A since 2018. Since that time, there have been 1,277 cases of hepatitis A reported in this Commonwealth, with 76% of these resulting in hospitalization, and 19 resulting in death. CDC. (2023). Person-to-person outbreaks of hepatitis A across the United States. Retrieved from https://stacks.cdc.gov/view/cdc/131998. Given this status, the Department proposes to require reporting of acute hepatitis A within 24 hours.

The CDC has listed hepatitis B, acute, as a nationally notifiable disease since 1966. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis B, Acute. Retrieved from https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/. Acute hepatitis B is transmitted via bodily fluids. Hepatitis B can start as a short-term infection and become chronic in some people. CDC. (2025). Hepatitis B Basics. Retrieved from https://www.cdc.gov/hepatitis-b/about/. Some people with acute hepatitis B have no symptoms at all, while others experience more severe illness requiring hospitalization. CDC. (2025). Viral

Hepatitis Basics. Retrieved from https://www.cdc.gov/hepatitis/about/. Many people with hepatitis B do not have symptoms, and do not know that they have it and therefore, can spread it to others. CDC. (2025). Hepatitis B Basics. Retrieved from https://www.cdc.gov/hepatitis-b/about/. From 2008-2019, twenty-five outbreaks of health care-associated hepatitis B were reported to the CDC, including 19 in long-term care facilities. CDC. (2023). Health Care-Associated Hepatitis B and C Outbreaks (≥ 2 cases) Reported to the CDC 2008-2019. Retrieved from https://archive.cdc.gov/www_cdc_gov/hepatitis/outbreaks/healthcarehepoutbreaktable.htm. The CDC estimates that this is only a fraction of the outbreaks that have possibly occurred because of the long incubation period and typically asymptomatic course of acute hepatitis B. *Id*. To protect vulnerable populations within health care facilities, the Department proposes to require reporting of acute hepatitis B cases within 24 hours, so that the Department can investigate and implement appropriate measures quickly.

The CDC has listed hepatitis B, chronic, as a nationally notifiable disease since 2003. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis B, Chronic. Retrieved from https://ndc.services.cdc.gov/conditions/hepatitis-b-chronic/. The CDC has listed hepatitis B, perinatal, as a nationally notifiable disease since 1995. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis B, Perinatal Infection. Retrieved from https://ndc.services.cdc.gov/conditions/hepatitis-b-perinatal-virus-infection/. The CDC has listed hepatitis C, acute, as a nationally notifiable disease since 1994. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis C, Acute. Retrieved from https://ndc.services.cdc.gov/conditions/hepatitis-c-acute/. The CDC has listed hepatitis C, chronic, as a nationally notifiable disease since 2003. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis C, Chronic. Retrieved from

https://ndc.services.cdc.gov/conditions/hepatitis-c-chronic/. The CDC has listed hepatitis C, perinatal, as a nationally notifiable disease since 2018. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Hepatitis C, Perinatal Infection. Retrieved from https://ndc.services.cdc.gov/conditions/hepatitis-c-perinatal-infection/. The Department proposes to add these types of hepatitis to the new chart and to propose the same timeframe as currently required for the reporting of viral, acute and chronic hepatitis, that is within 5 work days.

The Department proposes to add hepatitis D, acute and hepatitis D, chronic to the new chart. Hepatitis D is known as a "satellite virus" because it can only infect people who are also infected by the hepatitis B virus. Hepatitis D can be acute or chronic. CDC. (2024). Hepatitis D Basics. Retrieved from https://www.cdc.gov/hepatitis-d/about/index.html. It can be acquired simultaneously with hepatitis B or as a superinfection in those who have chronic hepatitis B. *Id*. Acute hepatitis D/B coinfections can resolve, but a superinfection can lead to rapid progression of already existing hepatitis B, resulting in liver cirrhosis and liver failure. *Id*. Most cases occur in people who migrate or travel to the United States. Hepatitis D is not currently a nationally notifiable condition. *Id*. Nonetheless, given the potential for severe infection, the Department proposes to add hepatitis D as a reportable condition to the new chart, and to require cases be reported within 5 work days.

The Department proposes to add hepatitis E, acute and hepatitis E, chronic to the new chart. In the United States, people have gotten sick with hepatitis E after eating raw or undercooked pork, venison, wild boar meat or shellfish. CDC. (2025). Hepatitis E Basics. Retrieved from https://www.cdc.gov/hepatitis-e/about/index.html. Cases in the United States have also occurred in people who have recently traveled to countries, with poor sanitation, where

hepatitis E is common. *Id*. Pregnant individuals, those who have had organ transplants, and those with compromised immune systems are at greater risk for more severe symptoms, including liver failure and death. *Id*. Hepatitis E is not currently a nationally notifiable condition. However, given the potential for severe infection, the Department proposes to add hepatitis E to the new chart, and to require cases to be reported within 5 work days.

Finally, the Department proposes to add hepatitis, viral, other types, to the new chart as a catch-all for any new types of hepatitis that may be identified in the future. The Department proposes to maintain the same time frame as currently required for the reporting of viral hepatitis.

Histoplasmosis

Health care practitioners and health care facilities are already required to report cases of histoplasmosis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add histoplasmosis to the new chart with no amendments to the existing method or timeframe for reporting.

Influenza and influenza-related deaths in children less than 18 years of age

The Department proposes to separate influenza into two types in the new chart: influenza (all types), confirmed by positive antigen or nucleic acid laboratory test or point-of-care rapid test; and influenza-related deaths in children less than 18 years of age. The proposed addition of language requiring confirmation of influenza to the reporting of all influenza cases aligns with existing § 27.21a(a)(2), which the Department proposes to delete, as well as CDC case definitions for reporting purposes. *See* CDC. (2021). Influenza-associated Hospitalizations 2012 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/influenza-

associated-hospitalizations-2012/; CDC. (2021). Influenza-associated Pediatric Mortality 2004 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/influenza-associated-pediatric-mortality-2004/.

The Department proposes to add influenza-related deaths in children as a separate reporting requirement to align with reporting requirements from the CDC. The CDC has required reporting of influenza-associated pediatric (defined as all persons less than 18 years old) mortality cases since 2004. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Influenza-associated Pediatric Mortality. Retrieved from https://ndc.services.cdc.gov/conditions/influenza-associated-pediatric-mortality/; CDC. (2021). Influenza-associated Pediatric Mortality 2004 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/influenza-associated-pediatric-mortality-2004/.

The Department proposes to retain the "within 5 work days" reporting requirement for influenza (all types), but to require reporting of influenza-related deaths in children within 24 hours. As of March 8, 2024, the CDC reported that 103 children had died thus far for the 2023-2024 flu season. CDC. (2024). More than 100 Flu-Related Deaths in Children Reported So Far This Season. https://www.cdc.gov/flu/whats-new/2023-2024-pediatric-flu-deaths.html. Nearly 90% of those were not vaccinated against the flu. *Id*. The Department proposes to require reporting of influenza-related deaths in children within 24 hours so that it may take appropriate measures to warn the public of the dangers of flu to children and the need for vaccinating children, particularly when there is an increase in deaths.

Leprosy (Hansen's disease)

Health care practitioners and health care facilities are already required to report cases of leprosy to the Department, within 5 work days, under existing subsection (b)(2). This reporting

is done through the Department's electronic disease surveillance system. The Department proposes to add leprosy to the new chart with no amendments to the existing method or timeframe for reporting.

Leptospirosis

Health care practitioners and health care facilities are already required to report cases of leptospirosis to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to add "leptospirosis" to the new chart and to rename it to "leptospirosis (*Leptospira interrogans*)" to include the specific bacterium most commonly responsible for the most severe infections in humans to the name. The Department proposes to require reporting of leptospirosis (*Leptospira interrogans*) no later than the next work day.

The CDC has listed leptospirosis (*Leptospira interrogans*) as a nationally notifiable disease since 2014. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Leptospirosis (*Leptospira interrogans*). Retrieved from https://ndc.services.cdc.gov/conditions/leptospirosis/. The bacteria that cause leptospirosis is spread through the urine of infected animals, such as cattle, pigs, horses, dogs, rodents and wild animals. CDC. (2025). About Leptospirosis. Retrieved from https://www.cdc.gov/leptospirosis/about/. Infection can occur through contact with urine, or other bodily fluid, from an infected animal, or through contact with water, soil or food contaminated by the urine of an infected animal. *Id*. Cases of leptospirosis can increase after hurricanes or floods due to exposure to contaminated water or through the use of contaminated water for drinking or bathing. CDC. (2025). Preventing Leptospirosis after Hurricanes or Flooding. Retrieved from https://www.cdc.gov/leptospirosis/prevention/. Leptospirosis can cause serious illness such as kidney or liver failure, meningitis, difficulty breathing and bleeding.

Id. Early treatment with antibiotics can prevent more severe illness and decrease the length of illness. *Id*.

Quick reporting and identification regarding the source of these cases is necessary so that the Department can take appropriate measures to protect the public, particularly where the source of contamination is a water supply that may infect multiple people. The Department therefore proposes to require that cases of leptospirosis be reported no later than the next work day.

Listeriosis

Health care practitioners and health care facilities are already required to report cases of listeriosis to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to instead require that cases of listeriosis be reported within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed listeriosis as a nationally notifiable disease since 2000. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Listeriosis. Retrieved from https://ndc.services.cdc.gov/conditions/listeriosis/. *Listeria* contaminates food products and is estimated by the CDC to be the third leading cause of death from foodborne illness in the United States. CDC. (2024). About *Listeria* Infection. Retrieved from https://www.cdc.gov/listeria/about/. Those who experience the most severe form of illness include the elderly, pregnant individuals and those with weakened immune systems. Illness during pregnancy usually results in miscarriage, stillbirth, premature delivery or life-threatening infection of the newborn. *Id*. Outbreaks of listeria do occur and have been linked to foods such as soft cheeses, raw milk products and deli products. CDC. (2025). Preventing *Listeria* Infection. Retrieved from https://www.cdc.gov/listeria/prevention/.

Quick reporting and identification regarding the source of these cases is necessary so that the Department can take appropriate measures to protect the public, particularly as the food source could be one that infects multiple people. The Department therefore proposes to require that cases of listeriosis be reported within 24 hours rather than 5 work days.

Lyme disease

The Department proposes not to add "Lyme disease" to the new chart. In June 2021, the Council of State and Territorial Epidemiologists (CSTE) met to discuss and approve changes to the Lyme disease surveillance case definition. Pennsylvania Department of Health. (2022). Lyme Disease Surveillance Changes and Testing Recommendations. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/han/2022-618-01-05-ADV-Lyme%20Disease.pdf. The previous case definition relied on reporting from both laboratories and health care providers. *Id*. Reporting from health care providers in high incidence states, such as this Commonwealth, does not contribute to the knowledge base of this disease. *Id*. Therefore, on January 1, 2022, this Commonwealth joined other high incidence Lyme disease states in shifting to a lab-only surveillance case definition for Lyme disease. *Id*. As such, health care practitioners and health care facilities are no longer required to report cases of Lyme disease in this Commonwealth. Laboratories are still required to report cases of Lyme disease, as noted in § 27.22(b) (relating to reporting of cases of clinical laboratories). Health care practitioners and health care facilities are also required to report other tickborne disease, as noted elsewhere in the chart.

Lymphogranuloma venereum

Health care practitioners and health care facilities are already required to report cases of lymphogranuloma venereum to the Department, within 5 work days, under existing subsection

(b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add lymphogranuloma venereum to the new chart with no amendments to the existing method or timeframe for reporting.

Malaria

Health care practitioners and health care facilities are already required to report cases of malaria to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add malaria to the new chart with no amendments to the existing method or timeframe for reporting.

Maple syrup urine disease (MSUD) in children under 5 years of age

The Department proposes not to add "maple syrup urine disease (MSUD) in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30, described below.

Meningitis (All types not caused by invasive Haemophilus influenza or Neisseria meningitis)

Health care practitioners and health care facilities are already required to report cases of meningitis (all types not caused by invasive Haemophilus influenza or Neisseria meningitis) to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add meningitis (all types not caused by invasive Haemophilus influenza or Neisseria meningitis) to the new chart with no amendments to the existing method or timeframe for reporting.

Mumps

Health care practitioners and health care facilities are already required to report cases of mumps to the Department, within 5 work days, under existing subsection (b)(2). This reporting

is done through the Department's electronic disease surveillance system. The Department proposes to add mumps to the new chart with no amendments to the existing method or timeframe for reporting.

Perinatal exposure of a newborn to HIV (effective October 18, 2002)

The Department proposes not to add perinatal exposure of a newborn to HIV to the new chart. Specific reporting requirements for perinatal exposure of a newborn to HIV exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of perinatal exposure of a newborn to HIV are in existing § 27.32a, it is not necessary to include them again in the new chart.

Pertussis (whooping cough)

Health care practitioners and health care facilities are already required to report cases of pertussis (whooping cough) to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to instead require that cases of pertussis be reported within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed pertussis as a nationally notifiable disease since 1973. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Pertussis / Whooping Cough (*Bordetella pertussis*). Retrieved from https://ndc.services.cdc.gov/conditions/pertussis/. Pertussis is a common, contagious respiratory illness that spreads easily from person to person, and results in frequent outbreaks in the United States. CDC. (2025). About Trends in Whooping Cough Disease. Retrieved from https://www.cdc.gov/pertussis/outbreaks/. Infants are most at risk from serious and deadly complications from pertussis. CDC. (2024). Symptoms of Whooping Cough. Retrieved from https://www.cdc.gov/pertussis/signs-symptoms/. However, teens and adults are also at risk of complications, such as pneumonia, from pertussis. *Id*. Since

October 2023, this Commonwealth has been seeing an increase in cases of pertussis amongst high school students and their close contacts, which is thought to be related to waning immunity. Pennsylvania Department of Health. (2023). Pertussis Update. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/han/2023-732-12-19-ADV-PertussisUpdate.pdf. Treatment for pertussis should begin as soon as possible, preferably before coughing begins. *Id*. Postexposure treatment is also recommended for those who are household contacts or at high risk of developing severe pertussis, as well as those who will have close contact with others at high risk. *Id*.

Quick reporting and identification of cases and those exposed to cases of pertussis is necessary so that the Department can take appropriate measures to protect the public from this rapidly spreading illness. The Department therefore proposes to require that cases of pertussis be reported within 24 hours rather than 5 work days.

Phenylketonuria (PKU) in children under 5 years of age

The Department proposes not to add "phenylketonuria (PKU) in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30, described below.

Primary congenital hypothyroidism in children under 5 years of age

The Department proposes not to add "primary congenital hypothyroidism in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30, described below.

Psittacosis (ornithosis)

Health care practitioners and health care facilities are already required to report cases of psittacosis (ornithosis) to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add psittacosis (ornithosis) to the new chart with no amendments to the existing method or timeframe for reporting.

Rickettsial diseases

Health care practitioners and health care facilities are already required to report cases of rickettsial diseases to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add "rickettsial disease" to the new chart but to rename it "rickettsial disease, not otherwise listed, including rickettsial pox and typhus" to cover reporting of rickettsial disease that is not listed separately, such as Rocky Mountain fever and anaplasmosis. with no amendments to the existing method or timeframe for reporting.

Rubella (German measles) and congenital rubella syndrome

Health care practitioners and health care facilities are already required to report cases of rubella (German measles) and congenital rubella syndrome to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to instead require that cases of rubella and congenital rubella syndrome be reported within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed rubella (German measles) and congenital rubella syndrome as nationally notifiable diseases since 1966. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Rubella / German Measles. Retrieved from https://ndc.services.cdc.gov/conditions/rubella/; CDC. (2021). National Notifiable Diseases

Surveillance System (NNDSS) – Rubella, Congenital Syndrome (CRS). Rubella is a vaccine-preventable viral illness. CDC. (2020). Manual for the Surveillance of Vaccine-Preventable Diseases, Chapter 14: Rubella. Retrieved from https://www.cdc.gov/surv-manual/php/table-of-contents/chapter-14-rubella.html. Rubella was eliminated from the United States in 2004 but can still be brought into the United States from other countries. CDC. (2025). Impact of U.S. MMR Vaccination Program. Retrieved from https://www.cdc.gov/rubella/vaccine-impact/. Rubella is very dangerous for pregnant individuals and their developing babies. CDC. (2020). Pregnancy and Rubella. Retrieved from https://www.cdc.gov/rubella/pregnancy/. Pregnant individuals who contract rubella are at risk for miscarriage or stillbirth, and their developing babies are at risk for congenital rubella syndrome (CRS) which results in severe birth defects, such as deafness, cataracts, heart defects, intellectual disabilities, liver and spleen damage, low birth weight, skin rash, glaucoma, brain damage, thyroid and other hormone problems and inflammation of the lungs. *Id*. While symptoms can be treated, there is no cure for CRS. *Id*. Therefore, it is advised that those who plan to become pregnant check with their doctors to make sure they are vaccinated against rubella. *Id*.

Prompt identification of cases of rubella is necessary to ensure that pregnant individuals are protected. CDC. (2020). Manual for the Surveillance of Vaccine-Preventable Diseases, Chapter 14: Rubella. Retrieved from https://www.cdc.gov/surv-manual/php/table-of-contents/chapter-14-rubella.html. The CDC classifies rubella as an "immediately notifiable disease," which requires reporting of any cases to the CDC within 24 hours. *Id*. The Department proposes to require reporting of rubella and congenital rubella syndrome within 24 hours to align with CDC requirements and to ensure that pregnant individuals are protected.

Salmonellosis

Health care practitioners and health care facilities are already required to report cases of Salmonellosis to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to instead require that cases of salmonellosis be reported within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed salmonellosis as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Salmonellosis (*Salmonella* spp.). Retrieved from https://ndc.services.cdc.gov/conditions/salmonellosis/. Salmonellosis is caused by the bacteria *Salmonella*. CDC. (2024). About *Salmonella* Infection. Retrieved from https://www.cdc.gov/salmonella/about/. The CDC estimates that *Salmonella* causes around 1.35 million illnesses, 26,500 hospitalizations and 420 deaths in the United States every year. *Id*. In addition, a multidrug-resistant strain of *Salmonella* has been identified by the CDC, which has demonstrated resistance to the antibiotic "azithromycin" which is typically used for treatment of salmonellosis. *See* CDC. (2022). A Strain of Multidrug-Resistant Salmonella Newport in Mexico. Retrieved from https://wwwnc.cdc.gov/travel/notices/level1/salmonella-newport-mexico; Plumb, I., et al. (2019). "Outbreak of Salmonella Newport Infections with Decreased Susceptibility to Azithromycin Linked to Beef Obtained in the United States and Soft Cheese Obtained in Mexico – United States, 2018-2019." Morbidity and Mortality Weekly Report (MMWR), 68(33); 713-717. Retrieved from https://www.cdc.gov/mmwr/volumes/68/wr/mm6833a1.htm.

Given the seriousness of the illness, and the potential harm that could be caused by a multidrug-resistant strain, the Department proposes to require reporting within 24 hours, so that the source of any outbreak can be identified quickly, and measures can be taken to protect the public.

Shigellosis

Health care practitioners and health care facilities are already required to report cases of shigellosis to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to instead require that cases of shigellosis be reported within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed shigellosis as a nationally notifiable disease since 1944. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Shigellosis. Retrieved from https://ndc.services.cdc.gov/conditions/shigellosis/. In 2023, the CDC issued a health advisory regarding an increase in extensively drug-resistant shigellosis in the United States. CDC. (2023). Increase in Extensively Drug-Resistant Shigellosis in the United States. Retrieved from https://emergency.cdc.gov/han/2023/han00486.asp. In 2022, about five percent of shigellosis cases reported to the CDC were extensively drug-resistant compared to zero percent in 2015. *Id*. Those infected with an extensively drug-resistant form of shigellosis have limited treatment options. *Id*. Shigellosis is easily transmitted, directly through person-to-person contact, or through indirect sources, such as contaminated food and water, and it only takes a small amount of *Shigella* to make someone ill. *Id*.

Given how easily shigellosis is transmitted, and the seriousness of extensively drug-resistant strains of this illness, the Department proposes to require reporting within 24 hours, so that the source of infection can be identified quickly, and measures can be taken to protect the public.

Sickle cell disease in children under 5 years of age

The Department proposes not to add "sickle cell disease in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30, described below.

Staphylococcus aureus, Vancomycin-resistant (or intermediate) invasive disease

Health care practitioners and health care facilities are already required to report cases of *staphylococcus aureus* to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to keep "*staphylococcus aureus*" in the new chart, but to rename it to "*staphylococcus aureus* infection or colonization, vancomycin-resistant or with intermediate resistance to vancomycin (VRSA or VISA)" to clarify that both symptomatic and asymptomatic versions of this infection must be reported. The Department proposes to require reporting of these cases within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed VRSA and VISA as nationally notifiable diseases since 2004. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Vancomycin-intermediate *Staphylococcus Aureus* and Vancomycin-resistant *Staphylococcus Aureus* (VISA/VRSA). Retrieved from https://ndc.services.cdc.gov/conditions/vancomycin-intermediate-staphylococcus-aureus-and-vancomycin-resistant-staphylococcus-aureus/. VISA and VRSA are types of antibiotic-resistant staph bacteria that are spread through close contact with infected persons or contaminated materials, such as bandages, and can be fatal if it enters the bloodstream. CDC. (2024). About Vancomycin-resistant *Staphylococcus aureus*. Retrieved from https://www.cdc.gov/staphylococcus-aureus/about/vancomycin-resistant-staph.html. The CDC recommends notification to local and state health departments while VRSA confirmatory testing is pending. CDC. (2015). Investigation and Control of Vancomycin-Resistant *Staphylococcus aureus* (VRSA): 2015 Update. Retrieved from

https://www.cdc.gov/staphylococcus-aureus/media/pdfs/vrsa-investigation-guide-p.pdf. The Department therefore proposes to require reporting of VISA and VRSA cases within 24 hours to comply with this guidance, and to ensure that appropriate measures are taken to protect the public.

Streptococcal invasive disease (group A)

Health care practitioners and health care facilities are already required to report cases of *Streptococcal* invasive disease (group A) to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to retain "*Streptococcal* invasive disease (group A)" in the new chart but to rename it to "*Streptococcal* invasive disease (group A), with organism identified in a normally sterile site" for clarity and to require reporting within 24 hours to the Department's electronic disease surveillance system.

Group A *Streptococcus* (GAS) bacteria is a leading case of infectious disease worldwide, resulting in a wide array of illnesses from mild, such as strep throat, to severe, such as sepsis, toxic shock syndrome and necrotizing fasciitis. Vekemans, J., et al. (2019). "The Path to Group A Streptococcus Vaccines: World Health Organization Research and Development Technology Roadmap and Preferred Product Characteristics." *Clinical Infectious Diseases*, 69(5), 877-883. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6695511/. Invasive group A *Streptococcus* (iGAS) is a severe form of Group A *Streptococcus*, which occurs in a normally sterile site, such as blood, pleural fluid, joint fluid or deep tissue. Dunne, E., et al. (2022). "Increasing Incidence of Invasive Group A *Streptococcus* Disease, Idaho, USA, 2008-2019." *Emerging Infectious Diseases*, 28(9), 1785-1795. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9423907/. In 2010, the Department was notified of a cluster of GAS and iGAS cases in a skilled nursing facility in this Commonwealth.

CDC. (2011). "Invasive Group A *Streptococcus* in a Skilled Nursing Facility – Pennsylvania, 2009-2010." *Morbidity and Mortality Weekly Report (MMWR)*, 60(42), 1445-1449. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6042a1.htm. Ten residents at the facility had GAS and thirteen had iGAS. *Id*. Of those with iGAS, all had to be hospitalized and two died. *Id*. Additionally, in 2022, the CDC issued a health advisory due to an increase in invasive group A *Streptococcus* (iGAS) infection in children in Colorado and other states. CDC. (2022). Increase in Pediatric Invasive Group A Streptococcal Infections. Retrieved from https://archive.cdc.gov/#/details?url=https://www.cdc.gov/han/2022/han00484.html. Given the severity of iGAS, the Department proposes to require reporting within 24 hours to ensure that appropriate measures are taken to protect the public.

Streptococcus pneumoniae, drug-resistant invasive disease

Health care practitioners and health care facilities are already required to report cases of *streptococcus pneumoniae*, drug-resistant invasive disease, to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to retain *streptococcus pneumoniae* in the new chart, but to rename it to "*streptococcus pneumoniae* (pneumococcus), recovered from any normally sterile body site," to include all cases of *streptococcus pneumoniae*, not just drug-resistant strains, in a normally sterile body site. The Department proposes this amendment to align with the Council of State and Territorial Epidemiologists' (CSTE) updated case definition, which now includes all invasive pneumococcal disease not just drug resistant streptococcus pneumoniae. CDC. (2020). Manual for the Surveillance of Vaccine-Preventable Diseases, Chapter 11: Pneumococcal. Retrieved from https://www.cdc.gov/surv-manual/php/table-of-contents/chapter-11-pneumococcal.html. The Department proposes to add "normally sterile body site" because isolating the organism from blood or other normally sterile

body sites is typically necessary for a definitive diagnosis of streptococcus pneumoniae infection. CDC. (2024). Clinical Overview of Pneumococcal Disease. Retrieved from https://www.cdc.gov/pneumococcal/hcp/clinical-overview/index.html. The Department proposes to add *streptococcus pneumoniae* (pneumococcus), recovered from any normally sterile body site to the new chart with no amendments to the existing method or timeframe for reporting.

Syphilis (all stages)

Health care practitioners and health care facilities are already required to report cases of syphilis to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to keep "syphilis" in the new chart but to rename it to "syphilis (all stages including congenital syphilis and syphilitic stillbirths)" for clarity and to require reporting within 24 hours to the Department's electronic disease surveillance system.

In 2023, in the United States, there were 209,253 cases of syphilis reported, largest number of cases reported since 1950, and a 1.0% increase from 2022. CDC. (2025). Sexually Transmitted Infections Surveillance, 2023. Retrieved from https://www.cdc.gov/sti-statistics/media/pdfs/2025/09/2023_STI_Surveillance_Report_FINAL_508.pdf. Out of this number, there were 3,755 cases of congenital syphilis, including 282 congenital syphilis-related stillbirths and infant deaths. *Id*. This represents a 30.6% increase since 2021 and is the highest reported rate since 1991. *Id*. Twenty-nine cases of congenital syphilis were reported in this Commonwealth (excluding Philadelphia) in 2023, the highest number reported since 1990. Pennsylvania Department of Health. (2024). Historic Increases in Reported Congenital Syphilis. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/han/2024-745-4-16-ADV-CongSyph.pdf.

Congenital syphilis occurs when a pregnant individual with syphilis passes the infection to the baby during pregnancy. CDC. (2024). About Congenital Syphilis. Retrieved from https://www.cdc.gov/syphilis/about/about-congenital-syphilis.html. Syphilis can result in miscarriage, stillbirth, premature birth, low birth weight or death shortly after birth. *Id*. Syphilis can be treated and cured with antibiotics. *Id*. It is important to be treated right away after a diagnosis of syphilis to prevent syphilis from progressing and in the case of a pregnant individual, to also protect the unborn child. *Id.*; CDC. (2022). About Syphilis. Retrieved from https://www.cdc.gov/syphilis/about/about-congenital-syphilis.html. It is also important that sex partners receive treatment. *Id*. The Department therefore proposes to require reporting of syphilis cases within 24 hours, rather than within 5 days, to ensure that appropriate measures are taken to protect those who could be exposed to syphilis.

Tetanus

Health care practitioners and health care facilities are already required to report cases of tetanus to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to instead require that cases of tetanus be reported within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed tetanus as a nationally notifiable disease since 1947. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Tetanus (*Clostridium tetani*). Retrieved from https://ndc.services.cdc.gov/conditions/tetanus/. Tetanus is a vaccine-preventable, noncommunicable infection, caused by *Clostridium tetani* bacteria, which enters the body through broken skin, usually injuries. CDC. (2025). Tetanus. Retrieved from https://www.cdc.gov/tetanus/about/index.html. Unvaccinated individuals, those older than 70 years of age, those with diabetes, those who are immunocompromised, and those using injection

medications are most at risk for tetanus. CDC. (2024). About Tetanus. Retrieved from https://www.cdc.gov/tetanus/about/index.html. Tetanus requires immediate treatment in a hospital. *Id*. Approximately 20%, or five cases, of the nationally reported pediatric tetanus infections in the United States from 2005 to 2015 were treated at Penn State Children's Hospital. Ahmed, B.S., et al. (2019). "Pediatric Tetanus in Central Pennsylvania." *Journal of the Pediatric Infectious Diseases Society*, 8(4), 358-360. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7317151/. All five children were unvaccinated; four of them were Amish. *Id*. Vaccine-preventable diseases occur more often in Amish children than non-Amish children. *Id*. While it is assumed that Amish individuals object to vaccinations, Amish community leaders have participated in vaccination programs, when there have been outbreaks. *Id*. Because tetanus continues to affect a disproportionate number of individuals in this Commonwealth, the Department proposes to require reporting of tetanus cases within 24 hours, rather than 5 days, to quickly identify the source of infection and to take measures, as appropriate, to protect the health and safety of those who are most vulnerable to this infection.

Toxic shock syndrome

Health care practitioners and health care facilities are already required to report cases of toxic shock syndrome to the Department, within 5 days, under existing subsection (b)(2). The Department proposes to add toxic shock syndrome to the new chart, but to rename it to "toxic shock syndrome, streptococcal and non-streptococcal" to make it clear that all cases of toxic shock syndrome must be reported to the Department. The Department also proposes to require that cases of toxic shock syndrome be reported within 24 hours, instead of 5 days, to the Department's electronic disease surveillance system.

The CDC has listed toxic shock syndrome (other than streptococcal) as a nationally notifiable disease since 1983. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Toxic Shock Syndrome (Other Than Streptococcal) (TSS). Retrieved from https://ndc.services.cdc.gov/conditions/toxic-shock-syndrome-other-than-streptococcal/. The CDC added streptococcal toxic shock syndrome as a nationally notifiable disease in 1995. CDC. (2021). Streptococcal Toxic Shock Syndrome (STSS) (*Streptococcus pyogenes*). Retrieved from https://ndc.services.cdc.gov/conditions/streptococcal-toxic-shock-syndrome/. Toxic shock syndrome is a rare, life-threatening bacterial infection, caused by toxin-producing strains of *Staphylococcus aureus* or *Streptococcus pyogenes*. Atchade, E., et al. (2024). "Toxic Shock Syndrome: A Literature Review." *Antibiotics (Basel)*, 13(1), 96. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10812596/. The mortality rate for staphylococcal toxic shock syndrome is estimated at approximately 5%, while the mortality rate for streptococcal toxic shock syndrome is much higher. *Id*. Approximately 3 out of 10 people with streptococcal toxic shock syndrome will die, even with treatment. CDC. (2024). About Streptococcal Toxic Shock Syndrome. Retrieved from https://www.cdc.gov/group-a-strep/about/streptococcal-toxic-shock-syndrome.html. Streptococcal toxic shock syndrome is more common in individuals who are 65 years of age or older and occurs more often in individuals who have open wounds or open sores. *Id*. While it is rare for someone with streptococcal toxic shock syndrome to spread the infection to another individual, a less severe group A strep infection can turn streptococcal toxic shock syndrome, and the bacteria that causes group A strep infection is contagious. *Id*.

Due to the deadly nature of toxic shock syndrome, the Department proposes to require reporting of these cases within 24 hours, rather than 5 days, so that it may act quickly to

determine the source of infection and take measures, as appropriate, to protect the public health and safety.

Toxoplasmosis

Health care practitioners and health care facilities are already required to report cases of toxoplasmosis to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add toxoplasmosis to the new chart with no amendments to the existing method or timeframe for reporting.

Trichinosis

Health care practitioners and health care facilities are already required to report cases of trichinosis to the Department, within 5 work days, under existing subsection (b)(2). The Department proposes to retain trichinosis in the new chart, but to rename it to "trichinellosis (trichinosis)" as "trichinellosis" is more commonly used to refer to infections caused by *Trichinella* larvae. CDC. (2024). About Trichinellosis. Retrieved from https://www.cdc.gov/trichinellosis/about/?CDC_AAref_Val=https://www.cdc.gov/parasites/trichinellosis/gen_info/faqs.html. The Department proposes to add trichinellosis (trichinosis), to the new chart with no amendments to the existing method or timeframe for reporting.

Tuberculosis, suspected or confirmed active disease (all sites)

Health care practitioners and health care facilities are already required to report cases of tuberculosis, suspected or confirmed active disease (all sites), to the Department, within 5 work days, under existing subsection (b)(2). This reporting is done through the Department's electronic disease surveillance system. The Department proposes to add tuberculosis, suspected

or confirmed active disease (all sites) to the new chart with no amendments to the existing method or timeframe for reporting.

Tularemia

Health care practitioners and health care facilities are already required to report cases of tularemia to the Department, within 24 hours, under existing subsection (b)(2). The Department proposes to require that cases of tularemia be reported immediately by telephone, instead, and within 24 hours to the Department's electronic disease surveillance system.

Tularemia is a potentially serious illness caused by *Francisella tularensis*, a bacterium that the CDC classifies as a "Category A" agent alongside variola (smallpox), *Yersinia pestis* (plague), filoviruses (Ebola and Marburg viruses), and *Clostridium botulinum* toxin (botulism). CDC. (2024). About Tularemia. Retrieved from https://www.cdc.gov/tularemia/about/index.html; CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category A" agents pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*. Because of this risk, the Department proposes to require that cases of tularemia be reported immediately by telephone as well as within 24 hours to the Department's electronic disease surveillance system.

Other diseases, infections and conditions not currently listed in subsection (b)

In addition to the above proposed amendments, the Department proposes to add the following diseases, infections and conditions to the new chart in subsection (b).

Acute Flaccid Myelitis (AFM)

The Department proposes to add acute flaccid myelitis (AFM) to the new chart and to require that cases of AFM be reported within 24 hours to the Department's electronic disease surveillance system.

AFM is an uncommon, serious neurological condition which affects the spinal cord and causes the muscles and reflexes in the body to become weak. CDC. (2024). About Acute Flaccid Myelitis. Retrieved from https://www.cdc.gov/acute-flaccid-myelitis/about/index.html. AFM primarily affects children, and is caused by viruses, including enteroviruses, flaviviruses, herpesviruses and adenoviruses. *Id*. The CDC has been tracking AFM since 2014 when the United States experienced an increase in the number of cases. CDC. (2024). What Causes Acute Flaccid Myelitis. Retrieved from https://www.cdc.gov/acute-flaccid-myelitis/causes/index.html. Increases also occurred in 2016 and 2018. *Id*. There is no specific treatment for AFM. *Id*. Given the severity of AFM, and its impact primarily on children, the Department proposes to track cases of AFM by requiring that cases be reported within 24 hours to the Department's electronic disease surveillance system.

Anaplasmosis

The Department proposes to add anaplasmosis to the new chart and to require that cases of anaplasmosis be reported within 5 days to the Department's electronic disease surveillance system.

The CDC listed anaplasmosis as a nationally notifiable disease in 2024. CDC. (2024). National Notifiable Diseases Surveillance System (NNDSS) – Anaplasmosis. Retrieved from https://ndc.services.cdc.gov/conditions/anaplasmosis/. Anaplasmosis is a bacterial disease that is spread to people through tick bites, primarily the blacklegged tick and the western blacklegged tick. CDC. (2024). About Anaplasmosis. Retrieved from

https://www.cdc.gov/anaplasmosis/about/. Early signs and symptoms of anaplasmosis are mild or moderate but can cause severe illness if treatment is delayed or an individual has other medical conditions or a weakened immune system. *Id*. The blacklegged tick is commonly found in the Northeast, including this Commonwealth, and the Midwestern United States. *Id*. Anaplasmosis is the second most commonly reported tickborne disease in this Commonwealth. Pennsylvania Department of Health. (2025). Tickborne Diseases - Dashboard. Retrieved from https://www.pa.gov/agencies/health/diseases-conditions/infectious-disease/vectorborne-diseases/tick-diseases.html.html. Cases have been increasing in recent years, and anaplasmosis infected ticks have been found in every county. *Id*. Given the potential for severe illness, and the CDC's desire to track cases of anaplasmosis, the Department proposes to require reporting of cases within 5 days to the Department's electronic disease surveillance system.

Arenavirus infections (including infections with Junin, Machupo, Guanarito and Sabia viruses)

The Department proposes to add arenaviruses, including infections with Junin, Machupo, Guanarito and Sabia viruses, to the new chart. The Department proposes that cases of arenaviruses be reported to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system.

Arenaviruses are a type of viral hemorrhagic fever that is transmitted through touching or breathing in air contaminated with urine, droppings or nesting materials from an infected rodent, being bitten or scratched by an infected rodent, eating food contaminated by an infected rodent's urine, droppings or saliva, or coming in contact with another person who has an arenavirus. CDC. (2024). Viral Hemorrhagic Fevers (VHSs) – About Viral Hemorrhagic Fevers. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/about/. Arenaviruses can cause severe disease in humans. *Id*. The CDC has listed Junin, Machupo, Guanarito and Sabia viruses as

reportable since 2010. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – New World Arenavirus – Junin Virus. Retrieved from https://ndc.services.cdc.gov/conditions/new-world-arenavirus-junin-virus/. Individuals with suspected or confirmed viral hemorrhagic fever, including arenaviruses, should remain in isolation until it is determined that they do not have viral hemorrhagic fever or they are no longer infectious. CDC. (2024). Viral Hemorrhagic Fevers (VHFs) – Public Health Management of People with Suspected or Confirmed VHF or High-Risk Exposures. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/php/public-health-strategy/people-with-suspected-or-confirmed-vhf-or-high-risk.html. Because of the need to isolate individuals who have this disease, the Department proposes to require immediate reporting of arenaviruses, including Junin, infections with Junin, Machupo, Guanarito and Sabia viruses, by telephone and within 24 hours to the Department's electronic disease surveillance system.

Arsenic level greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine

The Department proposes to add arsenic levels greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine ("arsenic exposure") to the new chart. The Department proposes to require reporting of these arsenic levels to the Department's electronic disease surveillance system within 24 hours.

Arsenic is found naturally in water and soil and is highly toxic in its inorganic form. World Health Organization. (2022). Arsenic. Retrieved from https://www.who.int/news-room/fact-sheets/detail/arsenic. Individuals are exposed to arsenic through drinking contaminated water, using contaminated water in food preparation and irrigation of food crops, and eating contaminated food. World Health Organization. (2022). Arsenic. Retrieved from

https://www.who.int/news-room/fact-sheets/detail/arsenic. Because arsenic is also used industrially, those who are exposed to farming chemicals, involved in glass manufacturing, work in construction and mines, recyclers, and those who perform smelting, are also at risk. World Health Organization. (2022). Arsenic. Retrieved from https://www.who.int/news-room/fact-sheets/detail/arsenic. Those who smoke tobacco are also at risk of exposure. World Health Organization. (2022). Arsenic. Retrieved from https://www.who.int/news-room/fact-sheets/detail/arsenic. Inorganic arsenic is a confirmed carcinogen. *Id*. Acute exposure may result in vomiting, abdominal pain and diarrhea, followed by numbness and tingling in the extremities, muscle cramping, and sometimes death. *Id*. Long-term exposure can cause skin, lung or bladder cancer, developmental defects, diabetes, pulmonary disease and cardiovascular disease. *Id*. Arsenic can also lead to adverse pregnancy outcomes, including infant mortality, and exposure in utero and early childhood can impact cognitive development, intelligence and memory, and can also result in physical conditions, such as cancer, lung disease, heart attack and kidney failure. *Id*.

There are more than one million private water wells in this Commonwealth, and approximately 20,000 new wells are drilled each year. These wells serve approximately 3.5 million people in rural areas of this Commonwealth. Penn State Extension. (2023). Private Water Systems FAQs. Retrieved from https://extension.psu.edu/private-water-systems-faqs. In 2022, the U.S. Geological Survey (USGS) collected and tested water samples from 578 groundwater wells in thirty counties in this Commonwealth. Penn State Extension. (2022). Removal of Arsenic from Wells in Pennsylvania. Retrieved from https://extension.psu.edu/removal-of-arsenic-from-wells-in-pennsylvania. Approximately 6% of

the wells had arsenic concentrations higher than United States Environmental Protection Agency standards. *Id*.

The Department proposes to require reporting of arsenic levels due to their toxicity, and the danger they present to public health, and to require reporting within 24 hours so that preventative measures can be employed, and efforts coordinated to protect public health and safety from further exposure. The Department proposes to specifically require reporting of arsenic levels greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine, to align with reporting requirements in other states, such as New Jersey. *See* New Jersey Department of Health. (2016). Clinical Laboratories. Retrieved from https://www.nj.gov/health/workplacehealthandsafety/occupational-health-surveillance/labregs.shtml.

Aspergillus fumigatus infections, azole-resistant

The Department proposes to add azole-resistant *Aspergillus fumigatus* infections to the new chart. The Department proposes to require that cases of azole-resistant *Aspergillus fumigatus* infections be reported, within 5 work days, to the Department's electronic disease surveillance system.

Aspergillosis is an infection caused by breathing in spores of the common mold, *Aspergillus*. CDC. (2024). Aspergillosis Basics. Retrieved from https://www.cdc.gov/aspergillosis/about/index.html. *Aspergillosis fumigatus* is a type of *Aspergillosis*, in which antimicrobial resistance is emerging, and is the most common cause of *Aspergillus* infections in humans. *Id*. The CDC placed *aspergillus fumigatus* on its 2019 report of antibiotic resistant threats in the United States. CDC. (2019). Antibiotic Resistance Threats in the United States: 2019. Retrieved from https://www.cdc.gov/antimicrobial-

resistance/media/pdfs/2019-ar-threats-report-508.pdf. *Aspergillosis fumigatus* can cause life-threatening infections in those who have weakened immune systems. *Id*. The CDC has limited tracking for aspergillosis fumigatus cases and is aware of only a few cases in the United States. *Id*. However, many more infections have been reported in other countries. *Id*. *Aspergillosis fumigatus* is difficult to detect because symptoms are similar to other respiratory infections. *Id*.

The Department proposes to require reporting of *aspergillus fumigatus* because of its resistance to antifungal medications. Because there have been few cases reported in the United States thus far, the Department proposes to only require reporting of these cases, within 5 work days, to the Department's electronic surveillance disease system.

Babesiosis

The Department proposes to add babesiosis to the new chart. The Department proposes to require that cases of babesiosis be reported, within 5 work days, to the Department's electronic disease surveillance system.

The CDC has listed babesiosis as a reportable disease since 2011. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Babesiosis (*Babesia* spp.). Retrieved from https://ndc.services.cdc.gov/conditions/babesiosis/. Babesiosis is a tickborne illness that is transmitted by the blacklegged (deer) tick. CDC. (2024). About Babesiosis. Retrieved from https://www.cdc.gov/babesiosis/about/index.html. The parasite spread from the blacklegged (deer) tick attacks an individual's red blood cells, which can lead to hemolytic anemia. *Id*. Additionally, babesiosis can become a serious, life-threatening illness for those who do not have a spleen, who have a weakened immune system, have serious health issues such as liver or kidney disease, or are 50 years of age or older. *Id*. The blacklegged (deer) tick can be found throughout this Commonwealth. Penn State Extension. (2023). Common Ticks and

Tick-borne Diseases in Pennsylvania. Retrieved from https://extension.psu.edu/common-ticks-and-tick-borne-diseases-in-pennsylvania. Excluding the year 2020 due to the COVID-19 pandemic, reported cases of *babesiosis* have been on the rise nationally. *See*, CDC. (2023). Surveillance for Babesiosis – United States, 2020. Retrieved from https://www.cdc.gov/parasites/babesiosis/resources/surveillance_babesiosis_US_2020d.pdf.

The Department proposes to require reporting of cases of babesiosis to align with CDC's list of reportable diseases. The Department proposes to require reporting of these cases, within 5 work days, to the Department's electronic surveillance disease system.

Bacillus cereus Biovar anthracis infection

The Department proposes to add *Bacillus cereus* Biovar *anthracis* to the new chart. The Department proposes to require that cases of *Bacillus cereus* Biovar *anthracis* be reported immediately, by telephone, and within 24 hours to the Department's electronic disease surveillance system.

In 2016, CDC added *Bacillus cereus* Biovar *anthracis* to the list of HHS select agents and toxins as a Tier 1 select agent. *See*, 81 FR 63138 (relating to possession, use, and transfer of select agents and toxins-addition of *Bacillus cereus* Biovar *anthracis* to the HHS list of select agents and toxins); 42 CFR 73.3(b) (relating to HHS select agents and toxins). *Bacillus cereus* Biovar *anthracis* is a spore-forming bacterium with similar virulence to *Bacillus anthracis*, or anthrax, which is also listed as a Tier 1 select agent. 81 FR 63138 at 63140—63141. The CDC therefore determined that it was necessary, as a matter of public health and national security, to add *Bacillus cereus* Biovar *anthracis* as a Tier 1 select agent. *Id.* at 63140—63142.

The Department proposes to align with the CDC and require reporting of *Bacillus cereus* Biovar *anthracis*. The Department proposes the same reporting requirements as anthrax, due to the similarities between *Bacillus cereus* Biovar *anthracis* and anthrax.

Bartonella infection, including "cat scratch fever"

The Department proposes to add *Bartonella* infection, including "cat scratch fever" to the new chart. The Department proposes to require reporting of *Bartonella* infection, within 5 work days, to the Department's electronic disease surveillance system.

Bartonella bacteria are spread to humans by fleas, body lice, sand flies or through contact with flea-infested animals. CDC. (2024). About Bartonella. Retrieved from https://www.cdc.gov/bartonella/about/index.html. The most common form of *Bartonella* infection is *Bartonella henselae* infection or "cat scratch fever," which is transmitted through scratches from cats who have fleas carrying the bacteria. *Id*. Other forms are *Bartonella quintana* infection, also known as trench fever, which is transmitted through the bite of the human body louse, and *Bartonella bacilliformis* infection, a rare infection transmitted by sand flies in some regions of South America. CDC. (2024). About *Bartonella quintana*. Retrieved from https://www.cdc.gov/bartonella/about/about-bartonella-quintana.html; CDC. (2024). About *Bartonella bacilliformis*. Retrieved from https://www.cdc.gov/bartonella/about/about-bartonella-bacilliformis.html. All forms of *Bartonella* infection can cause endocarditis, an infection of the heart, which requires antibiotic treatment and sometimes surgery to replace the heart valve. *Id*. The Department proposes to require reporting of Bartonella infection, within 5 work days, to the Department's electronic disease surveillance system.

Burkholderia infection melioidosis (B. pseudomallei) and glanders (B. mallei)

The Department proposes to add *burkholderia* infections melioidosis (*B. pseudomallei*) and glanders (*B. mallei*) to the new chart. The Department proposes to require reporting of these infections immediately by telephone and within 24 hours to the Department's electronic disease surveillance system.

Burkholderia pseudomallei (melioidosis) and *burkholderia mallei* (glanders) are listed as Category B select agents. CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. Agents in this category are moderately easy to disseminate, result in moderate morbidity rates and low mortality rates, and require specific enhancements of the CDC's diagnostic capacity and enhanced disease surveillance. *Id*. The bacteria that cause melioidosis can be found in soil and water and can be used as a weapon in a biological attack because the bacteria cannot be seen, smelled or tasted. CDC. (2024). Melioidosis and Bioterrorism. Retrieved from https://www.cdc.gov/melioidosis/bioterrorism/. It is also hard to diagnose because people may have similar symptoms as the flu or tuberculosis. *Id*. Without quick treatment, those with melioidosis can die. *Id*. Glanders has been eradicated in the developed world but has been used as a biological weapon in the past and could potentially be used in this manner again. Van Zandt, K.; Greer M.; and Gelhaus, H.C. (2013). "Glanders: an overview of infection in humans." Orphanet J. Rare Disease, 8:131. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3766238/. Because of the potential for the agents that result in these infections to be used as a biological weapon, the Department proposes to require immediate reporting by telephone, followed by reporting to the Department's electronic disease surveillance system within 24 hours.

Cadmium level greater or equal to 5 micrograms per liter (µg/L) of whole blood, or 3 micrograms per gram (µg/g) of creatinine

The Department proposes to add cadmium levels greater or equal to 5 micrograms per liter (ug/L) of whole blood, or 3 micrograms per gram (µg/g) of creatinine to the new chart. The Department proposes to require reporting of these cadmium levels to the Department's electronic disease surveillance system no later than the next work day.

Cadmium is a highly toxic carcinogenic that is harmful to most of the body's systems, but particularly to the lungs, bones, and kidneys. Charkiewicz, A., et al. (2023). "Cadmium Toxicity and Health Effects—A Brief Summary." *Molecules*, 28(18). Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC10537762/. Cadmium is used in the manufacturing of some batteries and solar cells, electroplating and silver soldering. *Id*. Construction workers, factory workers, and electronic recycling workers may be exposed to cadmium. *Id*.

The Department proposes to require reporting of cadmium levels due to the toxicity of this carcinogen, and the danger it presents to public health, and to require reporting no later than the next work day so that preventative measures can be employed, and decontamination efforts coordinated to protect public health and safety from further exposure. The Department proposes to specifically require reporting of cadmium levels greater or equal to 5 micrograms per liter (ug/L) of a person's whole blood or 3 micrograms per gram (ug/g) of creatinine. This proposed requirement aligns with reporting requirements from other states, such as New Jersey and Iowa. *See* State of New Jersey Department of Health. (2016). Clinical Laboratories. Retrieved from https://www.nj.gov/health/workplacehealthandsafety/occupational-health-surveillance/labregs.shtml; and Iowa Health & Human Services. (2024). Cadmium Poisoning.

Retrieved from https://hhs.iowa.gov/epi-manual-guide-surveillance-investigation-and-reporting/environmental-disease/cadmium-poisoning.

Candida auris

The Department proposes to add *Candida auris* to the new chart. The Department proposes to require reporting of *Candida auris* within 24 hours to the Department's electronic disease surveillance system.

The CDC added *Candida auris*, clinical to the national notifiable disease list in 2019 and *Candida auris*, screening to the list in 2023. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – *Candida auris*. Retrieved from https://ndc.services.cdc.gov/conditions/candida-auris/. Candida auris is a type of yeast that can cause a range of infections from superficial (skin) infections to more severe, life-threatening infections, such as bloodstream infections. CDC. (2024). About *C. auris*. https://www.cdc.gov/candida-auris/about/index.html. It is often resistant to anti-fungal medications and spreads easily among patients in health care facilities. *Id*.

The Department proposes to require reporting of *Candida auris* to align with the CDC. Because *Candida auris* is resistant to treatment and so easily spread, the Department proposes to require reporting within 24 hours to the Department's disease surveillance system, so that appropriate measures can be taken to prevent its' spread.

Carbapenemase-producing organisms, including carbapenem-resistant Enterobacterales, Pseudomonas species, and Acinetobacter species

The Department proposes to add Carbapenemase-Producing Organisms (CPO) to the new chart. The Department proposes to require reporting of CPO, within 24 hours, to the Department's electronic disease surveillance system.

The CDC added CPO to the national notifiable disease list in 2023. CDC. (2023). National Notifiable Diseases Surveillance System (NNDSS) – Carbapenemase-Producing Organisms (CPO). Retrieved from https://ndc.services.cdc.gov/conditions/carbapenemase-producing-organisms-cpo/. CPO are a group of multidrug resistant pathogens, which are difficult to treat and are associated with high mortality. CDC. (2023). Carbapenemase-Producing Organisms (CPO) 2023 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/carbapenemase-producing-organisms-cpo-2023/. The CDC considers CPO to be an urgent threat to public health, for which early detection and implementation of infection prevention and control strategies are needed to prevent further spread. *Id*.

The Department proposes to require reporting of CPO to align with the CDC. Because CPO is resistant to treatment and so easily spread, the Department proposes to require reporting within 24 hours to the Department's disease surveillance system, so that appropriate measures can be taken to prevent its' spread.

Carbon monoxide poisoning CO (carboxyhemoglobin) COHb greater or equal to 5% in blood

The Department proposes to add carbon monoxide poisoning CO (carboxyhemoglobin) COHb greater or equal to 5% in blood to the new chart. The Department proposes to require reporting of carbon monoxide poisoning to the Department's electronic disease surveillance system no later than the next work day.

Carbon monoxide is a colorless, odorless, nonirritating gas that is produced by many household items, including gas space heaters, woodstoves, gas stoves and fireplaces. CDC. (2021). Carbon Monoxide Poisoning 2014 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/carbon-monoxide-poisoning-2014/. Symptoms of

carbon monoxide poisoning include headache, dizziness, fatigue or weakness, nausea or vomiting, confusion, shortness of breath, chest pain and loss of consciousness. *Id*. Carbon monoxide poisoning is the leading cause of unintentional poisoning deaths in the United States, with approximately 450 deaths and 21,000 emergency department visits each year. *Id*.

The Department proposes to require reporting of COHb levels due to the toxicity of this gas, and the danger it presents to public health, and to require reporting no later than the next work day so that protective measures can be employed, and efforts coordinated to protect public health and safety from further exposure. The Department proposes to align, for reporting purposes, with the laboratory criteria for diagnosis, set forth by the CDC, which is a COHb level of greater than or equal to 5.0% as measured in a person by a blood sample.

Chikungunya virus infection

The Department proposes to add chikungunya virus infection to the new chart. The Department proposes to require reporting of chikungunya virus infection, within 24 hours, to the Department's electronic disease surveillance system. Chikungunya virus infection is a type of arbovirus, which the CDC has listed as nationally notifiable since 2015. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Chikungunya Virus Disease. Retrieved from https://ndc.services.cdc.gov/conditions/chikungunya-virus-disease/. The Department proposes to require reporting of cases of chikungunya virus infection separate from the reporting of other arboviruses, to align with the CDC. The Department proposes to require reporting of this infection, within 24 hours, to the Department's electronic disease surveillance system to align with already-existing reporting requirements for arboviruses.

Coccidioidomycosis

The Department proposes to add coccidioidomycosis to the new chart. The Department proposes to require reporting of coccidioidomycosis, within 5 work days, to the Department's electronic disease surveillance system.

The CDC has listed coccidioidomycosis as nationally notifiable since 2011. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Coccidioidomycosis/Valley Fever (*Coccidioides* spp.). Retrieved from https://ndc.services.cdc.gov/conditions/coccidioidomycosis/. Coccidioidomycosis, also known as Valley fever, is a lung infection caused by breathing in the spores from *Coccidioides*, a fungus that lives in the soil. CDC. (2024). About Valley Fever. Retrieved from https://www.cdc.gov/valley-fever/about/index.html. Activities that disturb the soil and dust, like windstorms or construction, increase the risk of breathing in these spores. CDC. (2024). Reducing Risk for Valley Fever. Retrieved from https://www.cdc.gov/valley-fever/prevention/index.html. Valley fever does not spread from person to person or between people and animals. CDC. (2024). Retrieved from https://www.cdc.gov/valley-fever/about/index.html. Valley fever is often misdiagnosed or undiagnosed because its' symptoms are like those of pneumonia. CDC. (2024). About Valley Fever. Retrieved from https://www.cdc.gov/valley-fever/about/index.html. Most cases of infections resolve on their own; those with severe infections are treated with antifungal medications. CDC. (2024). Treatment of Valley Fever. Retrieved from https://www.cdc.gov/valley-fever/treatment/index.html. However, approximately 5 to 10% of people who get Valley fever will develop serious or long-term problems in their lungs. CDC. (2024). Symptoms of Valley Fever. Retrieved from https://www.cdc.gov/valley-fever/signs-symptoms/index.html. In about 1% of cases, the infection will travel from the lungs to other parts of the body, such as the central

nervous system, skin, or bones and joints. *Id*. Outbreaks of Valley fever are rare. CDC. (2024). Areas with Valley Fever. Retrieved from https://www.cdc.gov/valley-fever/areas/index.html.

The Department proposes to require reporting of coccidioidomycosis to align with the CDC. Because Valley fever is not transmittable, and complications from Valley fever are rare, the Department proposes to require reporting of this infection, within 5 work days, to the Department's electronic disease surveillance system.

Coronavirus infection, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original severe acute respiratory syndrome (SARS)

The Department proposes to add coronavirus infection, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original severe acute respiratory syndrome (SARS), to the new chart. The Department proposes to require reporting of these cases, immediately by telephone and within 24 hours, to the Department's electronic disease surveillance system.

MERS is a viral respiratory illness caused by a coronavirus that is spread from camels to humans through direct physical contact. CDC. (2024). About Middle East Respiratory Syndrome (MERS). Retrieved from https://www.cdc.gov/mers/about/index.html. Limited human-to-human transmission is possible. *Id*. MERS causes severe respiratory disease, with many patients dying. *Id*.

The CDC has listed the original SARS (SARS-CoV) as a nationally identifiable disease since 2003. CDC. (2021). Severe Acute Respiratory Syndrome-associated Coronavirus Disease (SARS-CoV). Retrieved from https://ndc.services.cdc.gov/conditions/severe-acute-respiratory-syndrome-associated-coronavirus-disease/. COVID-19, a type of coronavirus, is caused by the SARS-CoV-2 virus. As seen with COVID-19, coronaviruses can continuously mutate, resulting

in variants that are different from the original. CDC. (2023). Variants Happen. Retrieved from https://www.cdc.gov/ncird/whats-new/variants-happen.html. Due to the evolving nature of coronaviruses, the Department proposes to require reporting of MERS, SARS, and other novel coronaviruses immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system so that the Department can take appropriate measures to protect the public in the event of an outbreak.

COVID-19 infection

The Department proposes to add COVID-19 to the new chart. The Department proposes to require reporting of COVID-19, within 5 work days, to the Department's electronic disease surveillance system. The CDC has listed COVID-19 as nationally notifiable since 2020. CDC. (2023). National Notifiable Diseases Surveillance System (NNDSS) – Coronavirus Disease 2019 (COVID-19). Retrieved from https://ndc.services.cdc.gov/conditions/coronavirus-disease-2019-covid-19/. The Department proposes to require reporting of COVID-19 cases to align with the CDC. Given the decline in the number of cases of COVID-19, the Department proposes to require reporting within 5 work days to the Department's electronic disease surveillance system. See, CDC. (2024). COVID Data Tracker. Retrieved from https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

Cronobacter infection, infant

The Department proposes to add *Cronobacter* infection, infant, to the new chart. The Department proposes to require reporting of infant *Cronobacter* infection, within 24 hours, to the Department's electronic disease surveillance system.

Cronobacter is a germ that is found naturally in the environment. CDC. (2024). About *Cronobacter* Infection. Retrieved from https://www.cdc.gov/cronobacter/about/index.html. It

can live in dry foods like powdered infant formula, herbal tea and starches, and in contaminated feeding items such as breast pump equipment. *Id*. Cronobacter infections can affect all ages but are most common in infants less than two months old and often result in death for this age group. *Id*. In 2022, a *Cronobacter* outbreak was linked to and led to the recall of certain powdered infant formula. CDC. (2024). *Cronobacter* Outbreak Linked to Powdered Infant Formula. Retrieved from https://www.cdc.gov/cronobacter/outbreaks/formula-2022/?CDC_AAref_Val=https://www.cdc.gov/cronobacter/outbreaks/source-date/index.html. The Department proposes to require cases of infant *Cronobacter* infection within 24 hours so that it may properly investigate these cases and take measures to prevent an outbreak of this deadly infection among infants.

Cyclosporiasis

The Department proposes to add cyclosporiasis to the new chart. The Department proposes to require reporting of cyclosporiasis, within 24 hours, to the Department's electronic disease surveillance system.

The CDC has listed cyclosporiasis as nationally notifiable since 1999. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Cyclosporiasis (*Cyclospora cayetanensis*). Retrieved from https://ndc.services.cdc.gov/conditions/coccidioidomycosis/. Cyclosporiasis is an intestinal illness caused by the microscopic parasite *Cyclospora cayetanensis*. CDC. (2024). About Cyclosporiasis. Retrieved from https://www.cdc.gov/cyclosporiasis/about/index.html. Individuals are infected by consuming food or water that contains this parasite. *Id*. Symptoms vary, with watery diarrhea being the most common symptom. CDC. (2024). Symptoms of Cyclosporiasis. Retrieved from https://www.cdc.gov/cyclosporiasis/signs-symptoms/index.html. The CDC monitors cases of

Cyclosporiasis to detect outbreaks linked to a common food source, so that appropriate action can be taken to prevent additional cases. CDC. (2024). Surveillance of Cyclosporiasis. Retrieved from https://www.cdc.gov/cyclosporiasis/php/surveillance/index.html.

The Department proposes to require reporting of cyclosporiasis to align with the CDC. Because swift action is needed to identify and prevent outbreaks, the Department proposes to require reporting of these cases within 24 hours to the Department's electronic disease surveillance system.

Dengue virus infection

The Department proposes to add dengue virus infection to the new chart. The Department proposes to require reporting of dengue virus infection, within 24 hours, to the Department's electronic disease surveillance system.

The CDC has listed dengue virus infections as nationally notifiable since 2010. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Dengue Virus Infections. Retrieved from https://ndc.services.cdc.gov/conditions/dengue-virus-infections/. Dengue virus infections are transmitted to humans by mosquitos. CDC. (2024). About Dengue. Retrieved from https://www.cdc.gov/dengue/about/index.html#cdc_disease_basics_types-types. Dengue cases resurged globally after the COVID-19 pandemic. CDC. (2024). Increased Risk of Dengue Virus Infections in the United States. Retrieved from https://emergency.cdc.gov/han/2024/han00511.asp. In 2024, more than 4.6 million cases and 4000 deaths were reported in the Americas region. *Id*. The CDC in June 2024 issued a Health Alert Network (HAN) Health Advisory to notify health care providers, public health authorities and the public of an increased risk of dengue virus infections in the United States. *Id*. The CDC indicated in the HAN that global incidence of dengue in 2024 has been the highest on record,

with many countries reporting higher than usual or record-breaking numbers of dengue cases. *Id*.

The Department proposes to require reporting of cases of dengue virus infection to align with the CDC. Due to the increasing number of cases, the Department proposes to require reporting of this infection, within 24 hours, to the Department's electronic disease surveillance system so that the Department.

Eastern equine encephalitis virus infection

The Department proposes to add Eastern equine encephalitis virus infection to the new chart. The Department proposes to require reporting of Eastern equine encephalitis virus infection, within 24 hours, to the Department's electronic disease surveillance system. Eastern equine encephalitis virus infection is a type of arbovirus, which the CDC has listed as nationally notifiable since 2005. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Eastern Equine Encephalitis Virus Disease. Retrieved from https://ndc.services.cdc.gov/conditions/eastern-equine-encephalitis-virus-disease/. The Department proposes to require reporting of cases of Eastern equine encephalitis virus infection separate from the reporting of other arboviruses, to align with the CDC. The Department proposes to require reporting of this infection, within 24 hours, to the Department's electronic disease surveillance system to align with already-existing reporting requirements for arboviruses.

Ebola infection

The Department proposes to add Ebola infection to the new chart. The Department proposes to require reporting of Ebola infection immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. Ebola is a type of viral hemorrhagic fever, which the CDC has listed as nationally notifiable since 2010. CDC. (2021). National

Notifiable Diseases Surveillance System (NNDSS) – Ebola Virus. Retrieved from https://ndc.services.cdc.gov/conditions/ebola-virus/. Ebola is classified as a "Category A" agent alongside anthrax (*Bacillus anthracis*), variola (smallpox), *Yersinia pestis* (plague), and *Clostridium botulinum* toxin (botulism). CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category A" agents pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*. Because of this risk, the Department proposes to require that cases of Ebola be reported immediately by telephone as well as within 24 hours to the Department's electronic disease surveillance system.

Ehrlichiosis

The Department proposes to add ehrlichiosis to the new chart. The Department proposes to require reporting of ehrlichiosis, within 5 work days, to the Department's electronic disease surveillance system. The CDC has listed ehrlichiosis as nationally notifiable since 1999. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Ehrlichiosis. Retrieved from https://ndc.services.cdc.gov/conditions/ehrlichiosis/. Ehrlichiosis is a tickborne illness transmitted by the lone star tick, primarily found in the south-central and eastern United States, and the blacklegged tick, found in the eastern United States. CDC. (2024). Ehrlichiosis: Causes and How It Spreads. Retrieved from https://www.cdc.gov/ehrlichiosis/causes/. The number of cases of ehrlichiosis has steadily climbed since the CDC first required reporting of the illness. CDC. (2024). Ehrlichiosis Epidemiology and Statistics – At a Glance. Retrieved from https://www.cdc.gov/ehrlichiosis/data-research/facts-stats/index.html. The Department proposes

to require reporting of cases of ehrlichiosis to align with the CDC. The Department proposes to require reporting of this infection, within 5 work days, to the Department's electronic disease surveillance system to track, investigate and determine appropriate measures to protect public health and safety.

Emerging disease or condition

The Department proposes to add emerging disease or condition to the new chart. The Department proposes to require reporting of an emerging disease or condition, within 24 hours, to the Department's electronic disease surveillance system. As noted in § 27.1 (relating to definitions), the Department proposes to define "emerging disease or condition" as "a disease that has been identified in a population for the first time, or that may have existed previously but is rapidly increasing in incidence in a geographic area or subset of the population." An emerging disease may be caused by "a previously undetected or unknown infectious agent," "a known agent that has spread to a new geographic location or population," "a previously known agent whose role in a specific disease has previously gone unrecognized," "a reemerging infectious disease, i.e., a reemergence of an agent whose incidence of disease has significantly declined in the past but whose incidence of disease has reappeared," "an infectious agent with antibiotic resistance patterns of public health significance or a disease with novel mechanisms of resistance, such as XDR and MDR diseases," and "use of or exposure to a product or substance that causes unexpected illness or a health-related event." The appearance of COVID-19 in 2020 is an example of the type of emerging disease or condition that would require reporting. The Department proposes reporting of emerging diseases and conditions within 24 hours to that it may quickly track, investigate, and determine appropriate measures to protect public health and safety.

Filovirus infections, not otherwise listed

The Department proposes to add filovirus infections, not otherwise listed, to the new chart. The Department proposes to require immediate reporting of filovirus infections, not otherwise listed, by telephone, and within 24 hours to the Department's electronic disease surveillance system.

Filoviruses are a type of viral hemorrhagic fever thought to be spread primarily by bats. CDC. (2024). About Viral Hemorrhagic Fevers. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/about/. Once introduced into the human population, filoviruses are easily spread through contact with an infected person's bodily fluids. *Id*. Thus, caretakers and health care providers who do not use appropriate personal protective equipment (PPE) are at higher risk of infection. *Id*. Ebola and Marburg, which will be listed separately in the new chart, are types of filoviruses. *Id*. Other types include the Sudan virus, Bundibugyo virus, Tai Forest virus, and Ravn virus. *Id*. These viruses would fall under the "filovirus infections, not otherwise listed" category. Persons with suspected of confirmed viral hemorrhagic fever, including filoviruses, should be isolated until it is determined that they do not have viral hemorrhagic fever or that they are no longer infectious. CDC. (2024). Public Health Management of People with Suspected or Confirmed VHF or High-Risk Exposures. Retrieved from https://www.cdc.gov/viral-hemorrhagic-fevers/php/public-health-strategy/people-with-suspected-or-confirmed-vhf-or-high-risk.html. Those with high-risk exposure to suspected or confirmed cases should be quarantined, monitored daily, and restricted from traveling commercial transport. *Id*. In addition, the CDC requests notification of those with high-risk exposure. *Id*.

The Department proposes to require reporting of filoviruses, not otherwise listed, to align with the CDC. Because of the need to take protective measures, such as quarantine or isolation,

to prevent the spread of these viruses, the Department proposes to require reporting immediately by telephone, and within 24 hours, to the Department's electronic disease surveillance system.

Free-living amoeba infection (including infections caused by Acanthamoeba spp., Balamuthia mandrillaris, and Naegleria fowleri)

The Department proposes to add free-living amebae infections, including infections caused by *Acanthamoeba* spp., *Balamuthia mandrillaris* and *Naegleria fowleri* to the new chart. The Department proposes to require immediate reporting of these infections by telephone, and within 24 hours to the Department's electronic disease surveillance system.

Acanthamoeba spp. has been found in soil; fresh, brackish and sea water; field-grown vegetables; sewage; swimming pools; contact lens supplies; medicinal pools; dental treatment units; dialysis machines; heating, ventilating and air conditioning systems; tap water; mammalian cell cultures; and vegetables. CDC. (2024). Free Living Amebic Infections. Retrieved from https://www.cdc.gov/dpdx/freelivingamebic/index.html. Entry can occur through the eye, the nasal passages to the lower respiratory tract, or ulcerated or broken skin. *Id*. *Balamuthia mandrillaris* has been found in soil and dust, as well as in autopsy specimens from infected humans and animals. *Id*. Entry can occur through the nasal passages to the lower respiratory tract or ulcerated or broken skin. *Id*. *Naegleria fowleri* has been found in fresh water, soil, thermal discharges of power plants, geothermal wells, and poorly chlorinated recreational and tap water. *Id*. Entry can occur through nasal mucosa, usually during swimming or sinus irrigation, and can migrate to the brain via the olfactory nerves. *Id*. These ameba species are free-living in the environment and are only opportunistically parasitic. *Id*. *Balamuthia mandrillaris* and *Naegleria fowleri* both have high fatality rates. *Id*. Given the potential deadliness of these infections, the Department proposes to require immediate reporting by

telephone and within 24 hours to the Department's electronic disease surveillance system, in order to investigate and take appropriate measures to protect the public health and safety.

Harmful algal bloom related illness

The Department proposes to add harmful agal bloom related illness to the new chart. The Department proposes to require reporting of these cases to the Department's electronic disease surveillance system no later than the next work day.

Symptoms of illnesses from harmful algal blooms depend on the type of harmful algal bloom a person is exposed to but can vary from mild to life-threatening. CDC. (2024). Harmful Agal Bloom (HAB)-Associated Illness: Symptoms of Illnesses Caused by Harmful Algal Blooms. Retrieved from https://www.cdc.gov/harmful-algal-blooms/signs-symptoms/index.html. Harmful algal blooms that grow in lakes or rivers cause different symptoms than those found in oceans or bays. *Id*. Common symptoms of harmful algal bloom related illnesses include stomach pain, rash, headache, coughing, watery eyes, nose irritation and sore throat. *Id*. More serious symptoms include liver damage, seizure and irregular heartbeat. *Id*. The Department proposes to require reporting of harmful algal bloom related illnesses and to require reporting no later than the next work day to identify the source of illness, and to take appropriate measures to protect the public health and safety, such as warning the public to stay clear of areas known to be associated with harmful algal bloom related illnesses.

Hemolytic uremic syndrome (HUS) with or without confirmation of E. coli infection

The Department proposes to add hemolytic uremic syndrome (HUS) with or without confirmation of E. coli infection to the new chart. The Department proposes to require reporting of these cases within 24 hours to the Department's electronic disease surveillance system.

HUS is a very serious complication of Shiga toxin-producing E. coli (STEC) infection, which can lead to kidney failure, permanent health problems and even death. CDC. (2024). Signs of Hemolytic Uremic Syndrome. Retrieved from https://www.cdc.gov/ecoli/signs-symptoms/hus.html. HUS is considered a medical emergency. *Id*. HUS can affect anyone, but most commonly occurs in children younger than 5 years of age. *Id*. Approximately 8 out of 10 children with HUS also have STEC. *Id*. Therefore, the Department proposes to require reporting of HUS within 24 hours to the Department's electronic disease surveillance system to align with the reporting requirements for STEC.

La Crosse encephalitis virus infection

The Department proposes to add La Crosse encephalitis virus infection to the new chart. The Department proposes to require reporting of La Crosse encephalitis virus infection , within 24 hours, to the Department's electronic disease surveillance system. La Crosse virus is a mosquito-borne illness, which can result in severe disease, including encephalitis or inflammation of the brain. CDC. (2024). About La Crosse. Retrieved from https://www.cdc.gov/la-crosse-encephalitis/about/index.html. La Crosse encephalitis is a rare, but severe disease that most often occurs in children under sixteen years of age. *Id*. La Crosse virus is the most prevalent arboviral infection in children. *Id*.; McJunkin, J.E., et al. (2001). "La Crosse Encephalitis in Children." *The New England Journal of Medicine*, vol. 344 (no. 11). Retrieved from https://www.nejm.org/doi/full/10.1056/NEJM200103153441103. There is no FDA-approved antiviral treatment for La Crosse encephalitis. *Id*. Given the deadly nature of this virus, and its impact on children, the Department proposes to require reporting of cases of La Crosse encephalitis virus infection separate from the reporting of other arboviruses. The Department proposes to require reporting of this infection, within 24 hours, to the Department's

electronic disease surveillance system to align with already-existing reporting requirements for arboviruses.

Marburg infection

The Department proposes to add Marburg infection to the new chart. The Department proposes to require reporting of Marburg infection immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. Marburg is a type of viral hemorrhagic fever, which the CDC has listed as nationally notifiable since 2010. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Marburg Virus. Retrieved from https://ndc.services.cdc.gov/conditions/marburg-virus/. Marburg is classified as a "Category A" agent alongside anthrax (*Bacillus anthracis*), variola (smallpox), *Yersinia pestis* (plague), and *Clostridium botulinum* toxin (botulism). CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category A" agents pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. *Id*. Because of this risk, the Department proposes to require that cases of Marburg be reported immediately by telephone as well as within 24 hours to the Department's electronic disease surveillance system.

Mercury level greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine, or greater or equal to 5 micrograms per gram (µg/g) in hair

The Department proposes to add mercury levels greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine, or greater or equal to 5

micrograms per gram (µg/g) in hair to the new chart. The Department proposes to require reporting of these levels to the Department's electronic disease surveillance system no later than the next work day.

Three types of mercury are harmful to humans: elemental mercury, inorganic mercury and organic mercury. Cleveland Clinic. (2022). Mercury Poisoning. Retrieved from https://my.clevelandclinic.org/health/diseases/23420-mercury-poisoning. Elemental mercury can be found.in thermometers, electrical switches, lightbulbs and dental fillings. *Id*. Inorganic mercury can be found in batteries, certain disinfectants and in chemistry labs. *Id*. Organic mercury can be found in coal fumes, fish and older antiseptics. *Id*. Mercury poisoning in the United States is rare. *Id*. The most severe cases of mercury poisoning have occurred in children, pregnant persons and those who are breastfeeding, and have been linked to consumption of large amounts of fish with high mercury content. *Id*. Symptoms of mercury poisoning vary by the type of exposure, but can consist of coughing, trouble breathing, nausea or vomiting, feeling numb or dull pain in the body, unsteadiness, double or blurry vision, memory loss, and seizures. *Id*. Exposure while pregnant can result in brain damage to the fetus. *Id*.

As recently as 2004, several individuals in Minnesota were exposed to mercury when two teenagers found two canning jars containing approximately 21 pounds of elemental mercury in a shed that was not secured. CDC. (2005). "Measuring Exposure to an Elemental Mercury Spill – Dakota County, Minnesota, 2004." *Morbidity and Mortality Weekly Report (MMWR)*, 54(06), 146-149. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5406a3.htm. The teens brought the jars back to their neighborhood, where other youths played with the mercury, threw it at each other, and splashed in a pool of it. *Id*. An investigation revealed that the teens attempted to ignite the mercury as well, potentially exposing them to fumes. *Id*. Due to the

quick response of a parent, who called police, the youths were able to be tested and decontaminated. *Id*.

The Department proposes to require reporting of mercury levels due to the toxicity of this metal, and the danger it presents to public health, and to require reporting no later than the next work day so that preventative measures can be employed, and efforts coordinated to protect public health and safety from further exposure. The Department proposes to specifically require reporting of mercury levels greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine, or greater or equal to 5 micrograms per gram (µg/g) in hair. These proposed levels align with reporting requirements in other states, such as New Jersey and Iowa.. *See* New Jersey Department of Health. (2016). Clinical Laboratories. Retrieved from https://www.nj.gov/health/workplacehealthandsafety/occupational-health-surveillance/labregs.shtml; and Iowa Health & Human Services. (2024). Mercury Poisoning. Retrieved from https://hhs.iowa.gov/epi-manual-guide-surveillance-investigation-and-reporting/environmental-disease/mercury-poisoning.

Monkeypox (mpox) infection

The Department proposes to add monkeypox (mpox) infection to the new chart. The Department proposes to require reporting of mpox within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed mpox as a nationally notifiable disease since 2022. CDC. (2023). National Notifiable Diseases Surveillance System (NNDSS) – Mpox Virus Infection. Retrieved from https://ndc.services.cdc.gov/conditions/mpox-virus-infection/. Mpox is caused by infection from the *Monkeypox virus* that results in a rash as well as other symptoms. CDC. (2025). About Mpox. Retrieved from https://www.cdc.gov/mpox/about/. Mpox is spread through direct

contact with infected wild animals, through close contact (including intimate or sexual contact) with a person who has mpox, and through contact with contaminated materials. CDC. (2025). How Mpox Spreads. Retrieved from https://www.cdc.gov/mpox/causes/. The ongoing global outbreak of mpox has caused more than 100,000 cases in 122 total countries, including 115 countries where mpox was not previously report. CDC. (2024). Mpox in the United States and Around the World: Current Situation. Retrieved from https://www.cdc.gov/mpox/situation-summary/index.html. In 2024 and thus far in 2025, there have been four reported cases of Clade I mpox in the United States, and around 200 or fewer cases of Clade II mpox since October 2024. *Id*.

The Department proposes to require reporting of mpox to align with the CDC. Because case counts are still high and vaccination rates are still low, it is imperative that the Department receive information regarding mpox cases quickly to take measures to prevent spread and a potential outbreak. Therefore, the Department proposes to require reporting of mpox, within 24 hours, to the Department's electronic disease surveillance system.

Nontuberculous mycobacteria, extrapulmonary infection

The Department proposes to add nontuberculous mycobacteria, extrapulmonary infection to the new chart. The Department proposes to require reporting of nontuberculous mycobacteria, extrapulmonary infection within 5 work days to the Department's electronic disease surveillance system.

Nontuberculous mycobacteria are bacteria found in soil, dust and water. CDC. (2024). About Nontuberculous Mycobacteria (NTM) Infections. Retrieved from https://www.cdc.gov/nontuberculous-mycobacteria/about/index.html. Exposure can occur through contaminated water, such as rivers and streams, municipal water sources, shower heads

and sink faucets, hydrotherapy equipment, ice machines and decorative fountains and water features. *Id*. Increased risk of exposure has been associated with tattoo parlors, nail salons, hot tubs or spas, and health care settings. *Id*. Extrapulmonary infection surveillance can help identify healthcare-associated infections and outbreaks faster. CDC. (2024). Clinical Overview of Nontuberculous Mycobacteria (NTM). Retrieved from https://www.cdc.gov/nontuberculous-mycobacteria/hcp/clinical-overview/. In 2015, the Department discovered a cluster of nontuberculous mycobacteria infections at one hospital that were linked by the CDC to a previously unrecognized source of transmission: heater-cooler devices used during cardiac surgery. Lyman, M. M., et al. "Invasive Nontuberculous Mycobacterial Infections among Cardiothoracic Surgical Patients Exposed to Heater-Cooler Devices." *Emerging Infectious Diseases*, 23(5), 796-805. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5403026/. In addition, as recently as 2022, the CDC issued a HAN Health Advisory due to multiple outbreaks of nontuberculous mycobacteria infections in children who received pulpotomies in pediatric dental clinics where the dental treatment water contained high levels of bacteria. CDC. (2022). Outbreaks of Mycobacteria Infections Highlight Importance of Maintaining and Monitoring Dental Waterlines. Retrieved from https://archive.cdc.gov/#/details?url=https://www.cdc.gov/han/2022/han00478.html. The Department proposes to require reporting of nontuberculous mycobacteria, extrapulmonary infection, within 5 work days, to detect outbreak of infection so that appropriate measures can be taken to identify the source of infection and thereby prevent any new infections from occurring.

Novel influenza A virus infection (infection with an influenza A virus that is different from circulating human influenza H1 and H3 viruses)

The Department proposes to add novel influenza A virus infection (infection with an influenza A virus that is different from circulating human influenza H1 and H3 viruses) to the new chart. The Department proposes to require reporting of these infections immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed novel influenza A virus infections as nationally notifiable since 2007. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Novel Influenza A Virus Infections. Retrieved from https://ndc.services.cdc.gov/conditions/novel-influenza-a-virus-infections/. The CDC defines this as a human case of infection with influenza A that is different from currently circulating human influenza H1 and H3 viruses. CDC. (2021). Novel Influenza A Virus Infections 2014 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/novel-influenza-a-virus-infections-2014/.

The Department proposes to require reporting of novel influenza A virus infections to align with the CDC. Because there is little to no pre-existing immunity for these infections, a rise in cases may signal the beginning of an influenza pandemic. CDC. (2021). Novel Influenza A Virus Infections 2014 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/novel-influenza-a-virus-infections-2014/. Rapid detection and reporting will ensure that the Department can act quickly, if needed, to implement public health and safety measures. The Department therefore proposes to require reporting of these infections immediately by telephone, and within 24 hours, to the Department's electronic disease surveillance system.

Orthopox virus infection, not otherwise listed

The Department proposes to add orthopox virus infection, not otherwise listed, to the new chart. The Department proposes to require that cases of orthopox virus be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system.

Orthopox viruses consist of smallpox and mpox, as well as other zoonotic orthopox viruses such as cowpox, camelpox, buffalopox, and other novel emerging orthopox viruses. Diaz, J. H. (2021). "The Disease Ecology, Epidemiology, Clinical Manifestations, Management, Prevention, and Control of Increasing Human Infections with Animal Orthopox viruses." Wilderness Environmental Medicine, 32(4), 528-536. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9628996/. The smallpox vaccine, which was thought to protect against other orthopox viruses, was discontinued after the WHO declared smallpox eradicated in 1980. *Id*. Waning immunity is thought to be a factor in the increasing prevalence of orthopox viruses, such as the recent mpox outbreak, in humans. *Id*. It is estimated that as many as 4 billion people may not be vaccinated against smallpox, and therefore be vulnerable to not only smallpox, but other orthopox viruses as well. *Id*. Early detection therefore is vital so that protective measures may be taken to prevent an outbreak. To align with proposed reporting requirements for smallpox and mpox, the Department proposes to require reporting of other orthopox virus infections immediately by telephone and within 24 hours to the Department's electronic disease surveillance system.

Pandrug-resistant (PDR) organism infection

The Department proposes to add pandrug-resistant (PDR) organism infection to the new chart. The Department proposes to require reporting of these infections within 24 hours to the Department's electronic disease surveillance system. As noted in § 27.1, the Department proposes to define "pandrug-resistant" as "non-susceptibility to all agents in all antimicrobial categories (*i.e.*, bacterial isolates are not susceptible to a clinically available drug)."

The CDC considers antimicrobial resistance to be an urgent global public health threat, killing at least 1.27 million worldwide, with nearly 5 million deaths occurring in 2019 alone.

CDC. (2024). About Antimicrobial Resistance. Retrieved from https://www.cdc.gov/antimicrobial-resistance/about/. Antibiotic resistance infections can spread between those who are symptomatic and non-symptomatic, and through a variety of ways, such as through close contact with another individual, through the air, through contaminated water, through contact with contaminated surfaces, through food, by touching animals, and through sexual contact. CDC. (2019). Antibiotic Resistance Threats in the United States: 2019. Retrieved from https://www.cdc.gov/antimicrobial-resistance/media/pdfs/2019-ar-threats-report-508.pdf. Antibiotic resistant infections are common in health care settings. *Id*. Because PDR infections are so contagious, the Department proposes to require reporting of PDR organism infections within 24 hours so that appropriate measures may be taken to protect the public.

Pesticide-related illness and injury, acute

The Department proposes to add acute pesticide-related illness and injury to the new chart. The Department proposes to require reporting of acute pesticide-related illnesses and injuries to the Department's electronic disease surveillance system, no later than the next work day.

The CDC has listed acute pesticide-related illness and injury as a nationally notifiable disease since 2010. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Pesticide-related Illness and Injury, Acute. Retrieved from https://ndc.services.cdc.gov/conditions/pesticide-related-illness-and-injury-acute/. As noted in § 27.1, the Department proposes to define the term "pesticide-related illness or injury" as "an acute adverse effect resulting from exposure to a pesticide product, as defined under section 136(u) of the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C.A. § 136(u)), including health effects due to an unpleasant odor, injury from explosion of a product, inhalation of smoke from a

burning product and allergic reaction." The Department proposes to adopt this definition from the CDC's 2010 surveillance case definition for "pesticide-related illness and injury, acute". *See*, Pesticide-related Illness and Injury, Acute 2010 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/pesticide-related-illness-and-injury-acute-2010/.

All sectors of the population are at risk of occupational and non-occupational pesticide-related illness and injury. HHS, CDC, National Institute for Occupational Safety and Health. (2005). Pesticide-related Illness and Injury Surveillance, A How-to Guide for State-based Programs. Retrieved from https://www.cdc.gov/niosh/docs/2006-102/pdfs/2006-102.pdf?id=10.26616/NIOSHPUB2006102. Although all pesticides must go through extensive testing before being placed on the market, testing cannot account for every scenario in which exposure could occur. *Id*. Surveillance, therefore, serves as an early warning system for any effects not detected through this testing. *Id*. An investigation may reveal a pattern of problems with the use of a particular pesticide, whether the illness or injury occurred despite being used according to the label, whether the illness or injury occurred because label instructions were not followed, and whether the instructions on the label are unclear, confusing, or inaccurate. *Id*. Investigation can also reveal whether certain populations or activities are at greater risk of illness or injury from a particular product. *Id*.

The Department proposes to require reporting of acute pesticide-related illnesses and injuries to align with the CDC. The Department proposes to require reporting to the Department's electronic disease surveillance system no later than the next work day to ensure that the Department can investigate these cases in a timely manner to identify any patterns in exposure.

Powassan virus infection

The Department proposes to add Powassan virus infection to the new chart. The Department proposes to require reporting of Powassan virus infection within 24 hours to the Department's electronic disease surveillance system. Powassan virus infection is a type of arbovirus, which the CDC has listed as nationally notifiable since 2005. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Powassan Virus Disease. Retrieved from https://ndc.services.cdc.gov/conditions/powassan-virus-disease/. The Department proposes to require reporting of cases of Powassan virus infection separate from the reporting of other arboviruses, to align with the CDC. The Department proposes to require reporting of this infection, within 24 hours, to the Department's electronic disease surveillance system to align with already-existing reporting requirements for arboviruses.

Q Fever, acute and chronic

The Department proposes to add acute and chronic Q fever to the new chart. The Department proposes to require reporting of acute and chronic Q fever immediately by telephone and within 24 hours to the Department's electronic disease surveillance system.

The CDC has listed acute and chronic Q fever as nationally notifiable since 2008. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Q Fever (Coxiella burnetii). Retrieved from https://ndc.services.cdc.gov/conditions/q-fever/. Humans become infected with Q fever by breathing in dust that has been contaminated by infected animal urine, feces, milk and birth products. CDC. (2024). About Q Fever. Retrieved from https://www.cdc.gov/q-fever/about/index.html. Veterinarians, meat processing plant workers, dairy workers, livestock ranchers, and researchers at facilities that house sheep and goats are at increased risk of exposure. *Id*. The symptoms of Q fever are like that of other diseases, making it difficult to diagnose. *Id*. Those who have no symptoms or have mild symptoms will recover

without antibiotic treatment. Those who are symptomatic need to be treated with an antibiotic. *Id*. Some individuals develop chronic Q fever, a life-threatening infection that requires several months of antibiotic treatment. *Id*.

Q fever is also classified as a "Category B" agent. CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category B" agents are moderately easy to disseminate, result in moderate morbidity rates and low mortality rates, and require enhanced disease surveillance. *Id*. Q fever is highly infectious, has been weaponized for use in biological warfare, and therefore is a potential terrorist threat. CDC. (2024). Bioterrorism and Q fever: The Threat. Retrieved from https://www.cdc.gov/q-fever/bioterrorism/index.html. Because of the potential for Q fever to be used as a biological weapon, the Department proposes to require that cases of Q fever, acute and chronic, be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system, so that appropriate measures can be taken to protect public health and safety.

Ricin poisoning

The Department proposes to add ricin poisoning to the new chart. The Department proposes to require reporting of ricin poisoning immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. Ricin is a poison found naturally in castor beans, which are processed throughout the world to make castor oil. CDC. (2018). Facts About Ricin. Retrieved from https://emergency.cdc.gov/agent/ricin/facts.asp. Ricin is part of the waste produced when castor oil is made. *Id*. Unintentional exposure to ricin is highly unlikely unless castor beans are ingested. *Id*. Ricin can be used as a terrorist or warfare agent and disseminated through air, food or water. *Id*. Death from ricin poisoning can occur within 36

to 72 hours of exposure depending on the amount and method of exposure. *Id*. Ricin toxin is classified as a "Category B" agent. CDC. (2018). Bioterrorism Agents/Diseases. Retrieved from http://medbox.iiab.me/modules/en-cdc/emergency.cdc.gov/agent/agentlist-category.asp. "Category B" agents are moderately easy to disseminate, result in moderate morbidity rates and low mortality rates, and require enhanced disease surveillance. *Id*. As recently as 2013, ricin was found in letters that were sent to former President Barack Obama. *See*, Payne, E., Smith, M. and Cratty, C. (2013). FBI Confirms Letters to Obama, Others Contained Ricin. Retrieved from https://www.cnn.com/2013/04/18/politics/tainted-letter-intercepted/index.html. Due to the deadly nature of ricin and its use as a biological weapon, to ensure prompt investigation, the Department proposes to require reporting of ricin poisoning immediately by telephone, and within 24 hours, to the Department's electronic disease surveillance system.

Silicosis

The Department proposes to add silicosis to the new chart. The Department proposes to require reporting of silicosis to the Department's electronic disease surveillance system, within 5 work days. The CDC has listed silicosis as a nationally notifiable disease since 2010. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Silicosis. Retrieved from https://ndc.services.cdc.gov/conditions/silicosis/. Silicosis is a progressive, incurable and potentially fatal disease that can be effectively prevented by limiting exposure to respirable crystalline silica dust. CDC. (2021). Silicosis 2010 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/silicosis-2010/. The Department proposes to require reporting of cases of silicosis to align with the CDC. The Department proposes to require reporting within 5 work days, to take appropriate measures based on when and where exposure occurred.

Smallpox vaccine-related adverse events

The Department proposes to add smallpox vaccine-related adverse events to the new chart. The Department proposes to require reporting of these events immediately by telephone. On January 24, 2003, DHHS implemented a preparedness program in which the smallpox vaccine was distributed to those who might be first responders during a biologic terrorism event. Case, C., et al. (2006). "Surveillance Guidelines for Smallpox Vaccine (vaccinia) Adverse Reactions." Morbidity and Mortality Weekly Report (MMWR), 55(RR01), 1-16. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5501a1.htm. As part of this program, CDC consulted with experts and established a surveillance case definition for the reporting of adverse events after smallpox vaccination. *Id*. This definition was based on adverse reactions that had been identified during the 1960s. *Id*. While the smallpox vaccine is considered generally safe and effective, adverse reactions can occur. CDC. (2024). Vaccine Adverse Events. Retrieved from https://www.cdc.gov/smallpox/hcp/vaccines/vaccine-adverse-events.html. The CDC provides consultation services to clinicians to help diagnose and manage patients with suspected smallpox vaccine adverse reactions. *Id*. The Department proposes to require reporting of smallpox vaccine-related adverse events to align with the CDC. The Department proposes to require reporting immediately by telephone so that it can appropriately assist health care providers in managing suspected adverse reactions.

Spotted fever rickettsiosis (Rocky Mountain fever)

The Department proposes to add spotted fever rickettsiosis, also known as Rocky Mountain fever, to the new chart. The Department proposes to require reporting of these cases, within 5 work days, to the Department's electronic disease surveillance system. The CDC has listed spotted fever rickettsiosis as a nationally notifiable disease since 2010. CDC. (2021).

National Notifiable Diseases Surveillance System (NNDSS) – Spotted Fever Rickettsiosis (*Rickettsia* spp.). Retrieved from https://ndc.services.cdc.gov/conditions/spotted-fever-rickettsiosis/. Rocky Mountain fever, a tickborne disease, is the most severe rickettsiosis in the United States. CDC. (2024). Clinical Signs and Symptoms. Retrieved from https://www.cdc.gov/rocky-mountain-spotted-fever/hcp/signs-symptoms/index.html. Rocky Mountain fever progresses rapidly and can be fatal within days if not properly treated. *Id*. In this Commonwealth, Rocky Mountain fever is transmitted by the American dog tick. CDC. (2024). About Rocky Mountain Spotted Fever. Retrieved from https://www.cdc.gov/rocky-mountain-spotted-fever/about/index.html. The Department proposes to require reporting of Rocky Mountain fever to align with the CDC. The Department proposes to require reporting within 5 work days to the Department's electronic disease surveillance system to align with the reporting of other, similar tickborne illnesses, such as babesiosis and ehrlichiosis.

St. Louis encephalitis virus infection

The Department proposes to add St. Louis encephalitis virus infection to the new chart. The Department proposes to require reporting of St. Louis encephalitis virus infection within 24 hours to the Department's electronic disease surveillance system. St. Louis encephalitis virus infection is a type of arbovirus, which the CDC has listed as nationally notifiable since 2005. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – St. Louis Encephalitis Virus Disease. Retrieved from https://ndc.services.cdc.gov/conditions/st-louis-encephalitis-virus-disease/. The Department proposes to require reporting of cases of St. Louis encephalitis virus infection separate from the reporting of other arboviruses, to align with the CDC. The Department proposes to require reporting of this infection, within 24 hours, to the

Department's electronic disease surveillance system to align with already-existing reporting requirements for arboviruses.

Tickborne diseases, excluding Lyme Disease and other conditions listed separately, and including disease due to Borrelia miyamotoi, Bourbon virus, and Heartland virus

The Department proposes to add a catch-all reporting requirement for tickborne diseases, excluding Lyme and other diseases specifically listed, in the new chart. The Department proposes to require reporting of these illnesses, within 24 hours, to the Department's electronic disease surveillance system. These diseases include Borrelia miyamotoi, transmitted by the blacklegged tick; Bourbon virus, transmitted by the lone star tick; and Heartland virus, also transmitted by the lone star tick. HHS, CDC. (2022). Tickborne Diseases of the United States: A Reference Manual for Healthcare Providers, 6th ed. Retrieved from https://www.cdc.gov/ticks/media/pdfs/2025/03/tickborne-diseases-manual-508.pdf?CDC_AAref_Val=https://www.cdc.gov/ticks/tickbornediseases/TickborneDiseases-P.pdf. Because these illnesses are not as prevalent, the Department proposes to require reporting within 24 hours so that any rise in these types of illnesses can be investigated quickly and adequate warning be provided to the public.

Tuberculosis infection, latent

The Department proposes to add latent tuberculosis infection to the new chart. The Department proposes to require reporting of latent tuberculosis infection, within 5 work days, to the Department's electronic disease surveillance system. Those with latent tuberculosis infections are infected with tuberculosis bacteria, but do not have active tuberculosis infection. CDC. (2024). Clinical Overview of Latent Tuberculosis Infection. Retrieved from https://www.cdc.gov/tb/hcp/clinical-overview/latent-tuberculosis-infection.html. Latent

tuberculosis infection can develop into tuberculosis disease if the bacteria become active and multiply. *Id*. Treatment for latent tuberculosis infection is effective for preventing tuberculosis disease. *Id*. Approximately 80% of tuberculosis cases in the United States is due to the progression of latent tuberculosis infection to tuberculosis disease. *Id*. Therefore, the CDC considers tracking of latent tuberculosis infections to be critical, although it does not presently require formal reporting of this disease. *Id*. As of April 2021, twenty-three states, require reporting of latent tuberculosis infection. CDC. (2024). Latent Tuberculosis Infection Laws. Retrieved from https://www.cdc.gov/tb/php/case-reporting/latent-tb-infection.html. Because of the high risk of latent tuberculosis developing into active tuberculosis disease, to protect public health and safety, the Department proposes to align with other states by requiring reporting of latent tuberculosis infection. The Department proposes to require reporting within 5 work days, to the Department's electronic disease surveillance system.

Vibrio infection other than cholera

The Department proposes to add *Vibrio* infections other than cholera to the new chart. The Department proposes to require reporting of these infections, within 24 hours, to the Department's electronic disease surveillance system. The CDC has listed vibriosis, other than cholera, as a nationally notifiable disease since 2007. CDC. (2021). Vibriosis (any species of the family *Vibrionaceae*, other than toxigenic *Vibrio cholerae* O1 or O139). Retrieved from https://ndc.services.cdc.gov/conditions/vibriosis/. *Vibrio* infections are caused by *Vibrio* bacteria, which live naturally in certain coastal waters. CDC. (2024). About *Vibrio* Infection. Retrieved from https://www.cdc.gov/vibrio/about/index.html. Vibriosis results from a person eating raw or undercooked shellfish, such as oysters, or when a person's open wound comes into contact with coastal waters. *Id*. Outbreaks of vibriosis from eating raw or uncooked shellfish

can occur. CDC. (2024). Outbreaks of Vibrio Infections. Retrieved from https://www.cdc.gov/vibrio/outbreaks/index.html. Wounds infected with *Vibrio* bacteria, that thrive in warm water, can result in necrotizing skin and soft tissue infection. CDC. (2023). Severe Vibrio vulnificus Infections in the United States Associated with Warming Coastal Waters. Retrieved from https://emergency.cdc.gov/han/2023/han00497.asp. The CDC issued a HAN Health Advisory in 2023, notifying health care providers of recent reports of fatal *Vibrio vulnificus* infections and to urge providers to consider *Vibrio vulnificus* as a possible cause of infected wounds that were exposed to coastal waters, particularly near the Gulf of Mexico and East Coast, and during periods of warmer coastal sea temperatures. *Id*. Given the risk of an outbreak with the foodborne version of *Vibrio*, and the danger associated with Vibrio infected wounds, to ensure that appropriate measures are taken to protect public health and safety, the Department proposes to require reporting of these infections, within 24 hours, to the Department's electronic disease surveillance system.

West Nile virus infection

The Department proposes to add West Nile virus infection to the new chart. The Department proposes to require reporting of West Nile virus infection within 24 hours to the Department's electronic disease surveillance system. West Nile virus infection is a type of flavivirus, which the CDC has listed as nationally notifiable since 2005. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – West Nile Virus Disease. Retrieved from https://ndc.services.cdc.gov/conditions/west-nile-virus-disease/. The Department proposes to require reporting of cases of West Nile virus infection to align with the CDC. The Department proposes to require reporting within 24 hours to the Department's electronic disease surveillance

system to align with the reporting of other, similar mosquito-borne illnesses, such as dengue virus.

Yellow fever virus infections

The Department proposes to add yellow fever virus infections to the new chart. The Department proposes to require reporting of yellow fever virus infections immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. The CDC has listed yellow fever as a nationally notifiable disease since 1944. CDC. (2021). Yellow Fever. Retrieved from https://ndc.services.cdc.gov/conditions/yellow-fever/. Yellow fever is a mosquito-borne virus found in Africa and South America. CDC. (2024). Yellow Fever: Causes and How It Spreads. Retrieved from https://www.cdc.gov/yellow-fever/causes-and-spread/index.html. Although yellow fever is somewhat rare in the United States, increasing numbers of travelers to and from endemic areas have resulted in heightened concern regarding the spread of the virus in the United States. CDC. (2021). Yellow Fever 2019 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/yellow-fever-2019/. The Department proposes to require reporting of yellow fever cases separately from other flaviviruses to align with the CDC. The Department proposes to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system to align with the reporting of other, similar mosquito-borne illnesses, such as dengue virus.

Yersiniosis

The Department proposes to add yersiniosis to the new chart. The Department proposes to require reporting of yersiniosis, within 24 hours, to the Department's electronic disease surveillance system. Yersiniosis is an illness caused by *Yersinia* bacteria. CDC. (2024). About *Yersinia* Infection. Retrieved from https://www.cdc.gov/yersinia/about/. Individuals contract

yersiniosis by eating contaminated food, especially raw or undercooked pork. *Id*. Individuals can also contract yersiniosis by through contact with a person who has prepared a pork product, drinking contaminated milk or untreated water, contact with animals, animal environments, animal feces, or contact with another person who has the infection. *Id*. Children are more susceptible to the illness than adults. *Id*. An outbreak of yersiniosis occurred in this Commonwealth as recently as 2019, due to consumption of pasteurized milk, which resulted in a voluntary recall of the product and temporary closure of the dairy to which the outbreak was traced. Gruber, J.F., et al. (2021). "*Yersinia enterocolitica* Outbreak Associated with Pasteurized Milk." *Foodborne Pathogens and Disease*, vol. 18(no. 17). Retrieved from https://www.liebertpub.com/doi/10.1089/fpd.2020.2924. The Department proposes to require reporting of yersiniosis within 24 hours to the Department's electronic disease surveillance system in order to protect public health and safety by timely investigating and determining the source of any potential outbreaks of this illness.

Zika virus infection

The Department proposes to add Zika virus infection to the new chart. The Department proposes to require reporting of zika virus infection, within 24 hours, to the Department's electronic disease surveillance system. The CDC has required reporting of Zika virus infection since 2016, but recently updated the surveillance case definition in 2024. CDC. (2021). National Notifiable Diseases Surveillance System (NNDSS) – Zika Virus Disease and Zika Virus Infection. Retrieved from https://ndc.services.cdc.gov/conditions/zika-virus-disease-and-zika-virus-infection/. Zika is a mosquito-borne illness that can also be sexually transmitted for up to three months from a Zika-infected person to their partner. CDC. (2024). Preventing Zika. Retrieved from https://www.cdc.gov/zika/prevention/index.html. Zika infection during

pregnancy can cause serious birth defects. CDC. (2024). Zika Symptoms and Complications. Retrieved from https://www.cdc.gov/zika/signs-symptoms/index.html. The Department proposes to require reporting of Zika cases to align with the CDC. The Department proposes to require reporting within 24 hours to the Department's electronic disease surveillance system to align with the reporting of other, similar mosquito-borne illnesses, such as dengue virus.

Subsection (c)

The Department proposes to replace the term "LMRO" with "the Department or local health department" throughout this subsection to the reporting requirements for school nurses and caregivers. Permitting school nurses and caregivers in a child care group setting to report unusual cases to either the Department or the local health department aligns with current practice.

Subsection (d)

The Department proposes to delete subsection (d), which requires reporting cancer cases in accordance with § 27.31 (relating to reporting of cases of cancer and brain-related tumors). The Department considers this subsection to be duplicative and unnecessary as the reporting requirements for cancer and brain-related tumors are addressed in § 27.31, with proposed amendments.

§ 27.22. Reporting of cases by clinical laboratories.

Subsection (a)

The Department proposes to delete the words "person who is in charge of a" before the words "clinical laboratory" as someone other than the person in charge of a clinical laboratory may report on the laboratory's behalf. The Department proposes stylistic amendments by replacing the words "microscopical, cultural, immunological, serological" with the words

"microscopic, culture, immunologic, serologic" and "virologic" with "viral." The Department proposes to delete the word "promptly" and the words "no later than the next work day after the close of business on the day on which the test was completed, except as otherwise noted in this chapter." The Department proposes to add the words "in the time and manner specified in subsection (b)" to reflect the proposed amendment to subsection (b), which will include a new chart, similar to the chart proposed in § 27.21a, above.

Subsection (b)

The Department proposes to replace the existing language in subsection (b) with new language and a new chart that lays out the etiologic agents, in alphabetical order, that are to be reported by clinical laboratories to the Department, along with the mechanism and timing for reporting.

The Department proposes to add language preceding the chart to indicate that "unless otherwise specified in this chapter or otherwise directed by the Department," a laboratory shall follow the timeframes and manner of reporting set forth in the chart. The proposed addition of "unless otherwise specified in this chapter" accounts for requirements for diseases, infections and conditions that are covered more thoroughly elsewhere in the regulations, such as AIDS and HIV, cancer and diseases of the newborn child. *See*, § 27.32a (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load results and HIV genotype test results, and perinatal exposure of newborns to HIV); § 27.30 (relating to reporting cases of certain diseases in the newborn child); and § 27.31 (relating to reporting cases of cancer and brain-related tumors).

The Department proposes the new chart format to make it easier for clinical laboratories to locate specific reporting requirements by searching within the chart alphabetically to

determine whether an etiologic agent needs to be reported, and on the same line, determine when and how to report. The new chart contains proposed additions, as well as proposed updates to the existing reporting requirements, which are described below.

Existing subsection (b) requires the reporting of the following diseases, infections and conditions to the Department, no later than the next work day: amebiasis; anthrax; an unusual cluster of isolates; arboviruses; botulism—all forms; brucellosis; CD4 T-lymphocyte counts and percentages; campylobacteriosis; cancer; chancroid; chickenpox (varicella); chlamydia trachomatis infections; cholera; congenital adrenal hyperplasia (CAH) in children under 5 years of age; Creutzfeldt-Jakob disease; cryptosporidiosis; diphtheria infections; enterohemorrhagic E. coli infections, or infections caused by other subtypes producing shiga-like toxin; galactosemia in children under 5 years of age; giardiasis; gonococcal infections; granuloma inguinale; HIV (Human Immunodeficiency Virus); HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results; *Haemophilus influenzae* infections—invasive from sterile sites; hantavirus; hepatitis, viral, acute and chronic cases; histoplasmosis; influenza; lead poisoning; legionellosis; leprosy (Hansen's disease); leptospirosis; listeriosis; Lyme disease; lymphogranuloma venereum; malaria; maple syrup urine disease (MSUD) in children under 5 years of age; measles (rubeola); meningococcal infections—invasive from sterile sites; mumps; pertussis; phenylketonuria (PKU) in children under 5 years of age; primary congenital hypothyroidism in children under 5 years of age; plague; poliomyelitis; psittacosis (ornithosis); rabies; respiratory syncytial virus; Rickettsial infections; rubella; salmonella; shigella; sickle cell disease in children under 5 years of age; staphylococcus aureus Vancomycin-resistant (or intermediate) invasive disease; streptococcus pneumoniae, drug-resistant invasive disease; syphilis; tetanus; toxoplasmosis; trichinosis; tuberculosis, confirmation of positive smears or

cultures, including results of drug susceptibility testing; tularemia; and typhoid. The Department proposes to delete existing subsection (b) and to add the etiologic agents that are currently listed to the new chart, but with some exceptions and amendments. Below is a description and explanation of proposed amendments starting first with the etiologic agents currently listed in regulation, followed by those which will be new.

Proposed amendments to existing etiologic agents listed in subsection (b)

Amebiasis

Clinical laboratories are already required to report cases of amebiasis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add amebiasis to the new chart, but to rename it to "*Entamoeba histolytica* (amebiasis)," to reflect the etiologic agent the lab would be testing for. The Department proposes to add *Entamoeba histolytica* to the new chart with no amendments to the existing method or timeframe for reporting.

Anthrax

Clinical laboratories are already required to report cases of anthrax to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add anthrax to the new chart, but to rename it to "*Bacillus anthracis* (anthrax)" to reflect the etiologic agent the lab would be testing for. The Department proposes to require that cases of *Bacillus anthracis* (anthrax) be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. The Department proposes this amendment to align with proposed § 27.21a, which will require health care practitioners and health care facilities to also report cases of anthrax immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. As noted in that section, the Department

proposes this amendment because *Bacillus anthracis* has been identified as a "Category A" agent that poses a risk to national security.

An unusual cluster of isolates

Clinical laboratories are already required to report unusual clusters of isolates to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add unusual clusters of isolates to the new chart, but to rename it to "unusual cluster of isolates, including organisms not explicitly reportable" to clarify that laboratories are to report all unusual clusters of isolates, not just those for organisms that are identified as reportable. The Department also proposes to require reporting of unusual clusters of isolates, including organisms not explicitly reportable, immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system.

Isolates are viruses that have been isolated from an infected host and propagated in culture. Racaniello, V. (2021). "Understanding virus isolates, variants, and strains." Virology Blog. Retrieved from https://virology.ws/2021/02/25/understanding-virus-isolates-variants-strains-and-more/. An unusual cluster of isolates could be indicative of a new virus or a variant of an existing virus. For example, isolates were used to identify the first cases of SARS-CoV-2 virus, or COVID-19, in patients in Wuhan in late 2019. *Id*. The Department proposes to require immediate reporting by telephone, followed by reporting to the Department's electronic disease surveillance system to take appropriate measures for public health and safety, such as education or isolation, in the event a new, emerging disease or potential outbreak is discovered through detection of an unusual cluster of isolates.

Arboviruses

Clinical laboratories are already required to report cases of arboviruses to the Department, no later than the next work day, under existing subsection (b). The Department proposes, in the new chart, to replace "arboviruses" with "arboviral infection, not otherwise listed" and to create separate requirements within the chart for arboviruses, such as yellow fever infection, West Nile virus and Zika virus that pose the most significant risk to public health. The Department proposes this amendment to align with proposed amendments for health care providers and facilities at § 27.21a, as described within that section. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Botulism – all forms

Clinical laboratories are already required to report cases of botulism to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add botulism to the new chart, but to rename it to "*Clostridium botulinum* (botulism) and botulinum toxin" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Brucella species

Clinical laboratories are already required to report cases of brucellosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add brucellosis to the new chart, but to rename it to *Brucella* species to reflect the etiologic agent that the laboratory would be testing for, and to require that cases of brucellosis be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system instead. The Department proposes this amendment to align with proposed §

27.21a, which will require health care practitioners and health care facilities to also report cases of brucellosis immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system.

CD4 T-lymphocyte counts and percentages

The Department proposes not to add CD4 T-lymphocyte counts and percentages to the new chart. Specific reporting requirements for CD4 T-lymphocyte counts and percentages exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of CD4 T-lymphocyte counts and percentages are in existing § 27.32a, it is not necessary to include them again in the new chart.

Campylobacteriosis

Clinical laboratories are already required to report cases of campylobacteriosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add campylobacteriosis to the new chart, but to rename it to "*Campylobacter* species" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Cancer

The Department proposes not to add cancer to the new chart. Specific reporting requirements for cancer exist currently in § 27.31 (reporting cases of cancer and brain-related tumors). Proposed amendments are described within that section. Because requirements for the reporting of cancer are in § 27.31, it is not necessary to include them again in the new chart.

Chancroid

Clinical laboratories are already required to report cases of chancroid to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add chancroid to the new chart, but to rename it to "*Haemophilus ducreyi* (chancroid)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Chickenpox (varicella)

Clinical laboratories are already required to report cases of chickenpox (varicella) to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add chickenpox (varicella) to the new chart, but to rename it to "varicella zoster virus" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Chlamydia trachomatis infection

Clinical laboratories are already required to report cases of chlamydia trachomatis infection to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add chlamydia trachomatis infection to the new chart, but to rename it to "*Chlamydia trachomatis*" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Cholera

Clinical laboratories are already required to report cases of cholera to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add

cholera to the new chart, but to rename it to "vibrio species, including *V. cholerae*, *V. parahaemolyticus* and *V. vulnificus*" to reflect the etiologic agent the lab would be testing for. This proposed amendment would also expand the scope of the current requirement, to include additional vibrio species. The Department proposes this to align with the proposed amendment, in § 27.21a, to require health care practitioners and facilities to report vibrio infections other than cholera in addition to cases of cholera. The Department proposes to require that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day, which aligns with the existing requirement for the reporting of cholera.

Congenital adrenal hyperplasia (CAH) in children under 5 years of age

The Department proposes not to add "congenital adrenal hyperplasia (CAH) in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30.

Creutzfeldt-Jakob disease

Clinical laboratories are already required to report cases of Creutzfeldt-Jakob disease to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add Creutzfeldt-Jakob disease to the new chart, but to rename it to "Creutzfeldt-Jakob disease proteins" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Cryptosporidiosis

Clinical laboratories are already required to report cases of cryptosporidiosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add cryptosporidiosis to the new chart, but to rename it to "*Cryptosporidium*" to

reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Diphtheria infection

Clinical laboratories are already required to report cases of diphtheria infection to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add diphtheria infection to the new chart, but to rename it to "*Corynebacterium diphtheriae* test results indicating acute infection (Diphtheria)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Enterohemorrhagic E. coli 0157 infections, or infections caused by other subtypes producing Shiga-like toxin

Clinical laboratories are already required to report cases of enterohemorrhagic E. coli 0157 infections, or infections caused by other subtypes producing Shiga-like toxin to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add enterohemorrhagic E. coli 0157 infections, or infections caused by other subtypes producing Shiga-like toxin to the new chart, but to rename it to "Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC) infection, or detection of Shiga toxin or Shiga toxin genes in a clinical specimen" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Galactosemia in children under 5 years of age

The Department proposes not to add "galactosemia in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30.

Giardiasis

Clinical laboratories are already required to report cases of giardiasis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add giardiasis to the new chart, but to rename it to "*Giardia lamblia* (or *Giardia duodenalis*)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Gonococcal infection

Clinical laboratories are already required to report cases of gonococcal infection to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add gonococcal infections to the new chart, but to rename it to "*Neisseria gonorrhoeae* (Gonorrhea**)**" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Granuloma inguinale

Clinical laboratories are already required to report cases of granuloma inguinale to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add granuloma inguinale to the new chart, but to rename it to "*Klebsiella granulomatis (*Donovania granulomatis*)* or Donovan bodies *(granuloma inguinale)*" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing

requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

HIV

The Department proposes not to add HIV to the new chart. Specific reporting requirements for HIV exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of HIV are in existing § 27.32a, it is not necessary to include them again in the new chart.

HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results

The Department proposes not to add HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results to the new chart. Specific reporting requirements for these results exist currently in § 27.32a. The Department does not propose any amendments to § 27.32a. Because requirements for the reporting of these test results are in existing § 27.32a, it is not necessary to include them again in the new chart.

Haemophilus influenzae infections—invasive from a sterile site

Clinical laboratories are already required to report cases of Haemophilus influenzae infections—invasive from a sterile site to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add Haemophilus influenzae infections—invasive from a sterile site to the new chart, but to rename it to "*Haemophilus influenzae* recovered from any normally sterile body site" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Hantavirus

Clinical laboratories are already required to report cases of hantavirus, no later than the next work day, to the Department under existing subsection (b). The Department proposes to add hantavirus to the new chart with no amendments to the existing method or timeframe for reporting.

Hepatitis, viral, acute and chronic cases

Clinical laboratories are already required to report cases of viral, acute and chronic hepatitis to the Department no later than the next work day. The Department proposes to add hepatitis to the new chart, but to separate reporting requirements for hepatitis by type, as follows: hepatitis A virus, test results indicating acute infection; hepatitis B virus, test results indicating acute, chronic or perinatal infection; hepatitis B virus, negative surface antigen and nucleic acid tests; hepatitis C virus, test results indicating acute, chronic or perinatal infection; hepatitis C virus, negative antibody and nucleic acid tests; hepatitis D (delta) virus, test results indicating acute or chronic infection; hepatitis E virus, test results indicating acute or chronic infection; and hepatitis, viral, other types. The Department proposes to add these types of hepatitis to the new chart to align with the requirements for reporting of hepatitis cases by health care practitioners and facilities. The Department proposes to add these types of hepatitis to the new chart with no amendments to the existing method or timeframe for reporting.

Histoplasmosis

Clinical laboratories are already required to report cases of histoplasmosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add histoplasmosis to the new chart, but to rename it to "*Histoplasma capsulatum*" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the

existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Influenza

Clinical laboratories are already required to report cases of influenza to the Department no later than the next work day. The Department proposes to add "influenza" to the new chart but to rename it to "influenza virus (all types), positive antigen or nucleic acid result" to properly identify the test result for a positive case of influenza rather than the virus itself. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Lead poisoning

Clinical laboratories are already required to report cases of lead poisoning to the Department no later than the next work day. The Department proposes to add "lead poisoning" to the new chart but to rename it to "lead results from persons of all ages, including negative results or results below the limited of detection, from venous or capillary blood specimens." The Department proposes this amendment to align with proposed amendments to the reporting requirements for lead poisoning for health care practitioners and health care facilities in § 27.21a. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Legionellosis

Clinical laboratories are already required to report cases of legionellosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add legionellosis to the new chart, but to rename it to "*Legionella* species" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing

requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Leprosy (Hansen's disease)

Clinical laboratories are already required to report cases of leprosy (Hansen's disease) to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add leprosy (Hansen's disease) to the new chart, but to rename it to "*Mycobacterium leprae* (leprosy, Hansen's disease)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Leptospirosis

Clinical laboratories are already required to report cases of leptospirosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add leptospirosis to the new chart, but to rename it to "*Leptospira interrogans*" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Listeriosis

Clinical laboratories are already required to report cases of listeriosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add listeriosis to the new chart, but to rename it to "*Listeria monocytogenes* or other pathogenic *Listeria* spp." to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Lyme disease

Clinical laboratories are already required to report cases of Lyme disease to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add Lyme disease to the new chart, but to rename it to "*Borrelia burgdorferi* (Lyme disease)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Lymphogranuloma venereum

Clinical laboratories are already required to report lymphogranuloma venereum, no later than the next work day, to the Department under existing subsection (b). The Department proposes to add lymphogranuloma venereum to the new chart with no amendments to the existing method or timeframe for reporting.

Malaria

Clinical laboratories are already required to report cases of malaria to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add malaria to the new chart, but to rename it to "*Plasmodium* species (Malaria)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Maple syrup urine disease (MSUD) in children under 5 years of age

The Department proposes not to add "maple syrup urine disease (MSUD) in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30, described below.

Measles (rubeola)

Clinical laboratories are already required to report cases of measles (rubeola) to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add measles (rubeola) to the new chart, but to rename it to "rubeola virus, test results indicating acute infection (Measles)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Meningococcal infections—invasive from sterile sites

Clinical laboratories are already required to report cases of meningococcal infections—invasive from sterile sites to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add meningococcal infections—invasive from sterile sites to the new chart, but to rename it to "*Neisseria meningitidis*, recovered from any normally sterile body site" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Mumps

Clinical laboratories are already required to report cases of mumps to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add mumps to the new chart, but to rename it to "mumps virus, test results indicating acute infection" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Pertussis

Clinical laboratories are already required to report cases of pertussis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add pertussis to the new chart, but to rename it to "*Bordetella pertussis* (pertussis)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Phenylketonuria (PKU) in children under 5 years of age

The Department proposes not to add "phenylketonuria (PKU) in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30, described below.

Primary congenital hypothyroidism in children under 5 years of age

The Department proposes not to add "primary congenital hypothyroidism in children under 5 years of age" to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30 (relating to reporting cases of certain diseases in the newborn child), described below.

Plague

Clinical laboratories are already required to report cases of plague to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add plague to the new chart, but to rename it to "*Yersinia pestis* (plague)" to reflect the etiologic agent the lab would be testing for. The Department proposes to require that cases of *Yersinia pestis* (plague) be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. The Department proposes this amendment to align with proposed § 27.21a, which will require health care practitioners and health care facilities to also

report cases of plague immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. As noted in that section, the Department proposes this amendment because *Yersinia pestis* has been identified as a "Category A" agent that poses a risk to national security.

Poliomyelitis

Clinical laboratories are already required to report cases of poliomyelitis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add poliomyelitis to the new chart, but to rename it to "polio virus, test results indicating acute infection" to reflect the etiologic agent the lab would be testing for. The Department proposes to require that test results indicating acute infection of polio virus be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. The Department proposes this amendment to align with proposed § 27.21a, which will require health care practitioners and health care facilities to also report cases of poliomyelitis immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. As noted in that section, the Department proposes this amendment to align with the CDC.

Psittacosis (ornithosis)

Clinical laboratories are already required to report cases of psittacosis (ornithosis) to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add psittacosis (ornithosis) to the new chart, but to rename it to "*Chlamydia psittaci* (psittacosis or ornithosis)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Rabies

Clinical laboratories are already required to report cases of rabies to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add rabies to the new chart, but to rename it to "rabies virus in humans" to reflect the etiologic agent the lab would be testing for. The Department proposes to require that rabies virus in humans be reported immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. The Department proposes this amendment to align with proposed § 27.21a, which will require health care practitioners and health care facilities to also report cases of rabies immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. As noted in that section, the Department proposes more stringent reporting requirements given the near 100% mortality rate associated with rabies, to prevent any spread of the disease.

Respiratory syncytial virus

Clinical laboratories are already required to report respiratory syncytial virus, no later than the next work day, to the Department under existing subsection (b). The Department proposes to add respiratory syncytial virus to the new chart with no amendments to the existing method or timeframe for reporting.

Rickettsial infections

Clinical laboratories are already required to report cases of rickettsial infection to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add rickettsial infection to the new chart, but to rename it to "*Rickettsia*, including *R. rickettsii* (spotted fever rickettsiosis), *R. akari*. (Rickettsialpox), *R. typhi*, *R. felis*, and *R. prowazekii* (typhus)" to reflect the etiologic agent the lab would be testing for. The Department

proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Rubella

Clinical laboratories are already required to report cases of rubella to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add rubella to the new chart, but to rename it to "rubella virus, test results indicating acute infection (German Measles)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Salmonella

Clinical laboratories are already required to report cases of salmonella to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add salmonella to the new chart, but to rename it to "*Salmonella* species" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Shigella

Clinical laboratories are already required to report cases of shigella to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add shigella to the new chart, but to rename it to "*Shigella* species" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Sickle cell disease in children under 5 years of age

The Department proposes not to add sickle cell disease in children under 5 years of age to the new chart. Requirements for the reporting of cases in newborns will be addressed in proposed § 27.30 (relating to reporting cases of certain diseases in the newborn child), described below.

Staphylococcus aureus Vancomycin-resistant (or intermediate) invasive disease

Clinical laboratories are already required to report cases of staphylococcus aureus vancomycin-resistant (or intermediate) invasive disease to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add staphylococcus aureus vancomycin-resistant (or intermediate) invasive disease to the new chart, but to rename it to "*staphylococcus aureus* resistant or with intermediate sensitivity to vancomycin (VRSA or VISA)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Streptococcus pneumoniae, drug-resistant invasive disease

Clinical laboratories are already required to report cases of streptococcus pneumoniae, drug-resistant invasive disease, to the Department, no later than the next work day, under existing subsection (b). The Department proposes to retain streptococcus pneumoniae in the new chart, but to rename it to "*streptococcus pneumoniae* (pneumococcus), recovered from any normally sterile body site," to include all cases of *streptococcus pneumoniae*, not just drug-resistant strains, in a normally sterile body site. The Department proposes this amendment to align with the reporting requirements for health care practitioners and health care facilities in proposed § 27.21a. The Department proposes to retain the existing requirement that labs report

cases of *streptococcus pneumoniae* to the Department's electronic disease surveillance system, no later than the next work day.

Syphilis

Clinical laboratories are already required to report cases of syphilis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add syphilis to the new chart, but to rename it to "*Treponema pallidum* (syphilis)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Tetanus

Clinical laboratories are already required to report cases of tetanus to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add tetanus to the new chart, but to rename it to "*Clostridium tetani* (tetanus)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Toxoplasmosis

Clinical laboratories are already required to report cases of toxoplasmosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add toxoplasmosis to the new chart, but to rename it to "*Toxoplasma*" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Trichinosis

Clinical laboratories are already required to report cases of trichinosis to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add trichinosis to the new chart, but to rename it to "*Trichinella* species" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Tuberculosis, confirmation of positive smears or cultures, including results of drug susceptibility testing

Clinical laboratories are already required to report confirmation of positive smears or cultures, including results of drug susceptibility testing, for tuberculosis, to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add "tuberculosis, confirmation of positive smears or cultures, including results of drug susceptibility testing" to the new chart, but to separate it into three separate reporting requirements as follows: acid fast bacilli, positive smears, *mycobacterium tuberculosis* or tuberculosis complex, by nucleic acid amplification, culture or culture-independent diagnostic test including interferon gamma-release assays (IGRAs); and *mycobacterium tuberculosis* or tuberculosis complex, all results of drug susceptibility testing. An acid fast bacilli, positive smear indicates tuberculosis. The Department proposes this amendment to not only reflect the etiologic agent the laboratory would be testing for, but to also make it clear what types of test results need to be reported. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Tularemia

Clinical laboratories are already required to report cases of tularemia to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add tularemia to the new chart, but to rename it to "*Francisella tularensis* (Tularemia)" to reflect the etiologic agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Typhoid

Clinical laboratories are already required to report cases of typhoid to the Department, no later than the next work day, under existing subsection (b). The Department proposes to add tularemia to the new chart, but to rename it to "*Salmonella* Typhi (typhoid fever) or *Salmonella* Paratyphi (paratyphoid fever)" to reflect the agent the lab would be testing for. The Department proposes to retain the existing requirement that labs report these cases to the Department's electronic disease surveillance system, no later than the next work day.

Proposed additions to list of etiologic agents

In addition to the above proposed amendments, the Department proposes to add the following to the new chart in subsection (b).

Adenoviruses

The Department proposes to add adenoviruses to the new chart and to require clinical laboratories to report findings of adenoviruses to the Department's electronic disease surveillance system, no later than the next work day. Adenoviruses are common and typically cause mild cold or flu-like symptoms but can cause severe illness in those with weakened immune systems or existing respiratory or cardiac disease. CDC. (2024). About Adenovirus.

Retrieved from https://www.cdc.gov/adenovirus/about/index.html. The Department proposes to require clinical laboratories, but not health care practitioners or health care facilities to report cases of adenoviruses because generally only severe cases would prompt a provider or facility to send a specimen to the lab for testing and tracking such cases is needed to protect public health, for example, providing education and other measures, in the event that there are a large number of severe cases being reported.

Anaplasma species

The Department proposes to add *Anaplasma* species to the new chart and to require clinical laboratories to report findings of *Anaplasma* species to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Anaplasma* species to align with the proposed addition of anaplasmosis to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other proposed reporting requirements for clinical laboratories.

Arenaviruses (including Junin, Machupo, Guanarito and Sabia)

The Department proposes to add arenaviruses (including Junin, Machupo, Guanarito and Sabia) to the new chart and to require clinical laboratories to report findings of these viruses to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of arenaviruses, and to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system to align with the proposed addition of arenavirus infections to the reporting requirements for health care providers and facilities in § 27.21a(b).

As noted in § 27.21a(b), the need to isolate individuals who have arenavirus infections necessitates faster reporting.

Arsenic level greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine

The Department proposes to add arsenic levels greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine to the new chart and to require clinical laboratories to report these levels to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of arsenic levels, to align with the proposed addition of arsenic levels to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Aspergillus fumigatus, azole-resistant

The Department proposes to add *Aspergillus fumigates*, azole-resistant, to the new chart and to require clinical laboratories to report findings of *Aspergillus fumigates*, azole-resistant, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Aspergillus fumigates*, azole-resistant, to align with the proposed addition of *Aspergillus fumigates* infections, azole-resistant, to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other proposed reporting requirements for clinical laboratories.

Babesia microti

The Department proposes to add *Babesia microti*, to the new chart and to require clinical laboratories to report findings of *Babesia microti*, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Babesia microti*, to align with the proposed addition of babesiosis to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align with other reporting requirements for clinical laboratories.

Bacillus cereus Biovar anthracis

The Department proposes to add *Bacillus cereus* Biovar *anthracis* to the new chart and to require clinical laboratories to report findings of *Bacillus cereus* Biovar *anthracis* to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of *Bacillus cereus* Biovar *anthracis* to align with the proposed addition of *Bacillus cereus* Biovar *anthracis* infections to the reporting requirements for health care providers and facilities in § 27.21a(b). As noted in § 27.21a(b), *Bacillus cereus* Biovar *anthracis* is classified as a Tier 1 select agent, similar in nature to *Bacillus anthracis*, a Tier 1 and Category A agent that causes anthrax. Due to the similarities between *Bacillus cereus* Biovar *anthracis* and *Bacillus anthracis*, the Department proposes to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system, which aligns with the proposed reporting requirements for health care providers and facilities in § 27.21a(b).

Bartonella species

The Department proposes to add *Bartonella* species, to the new chart and to require clinical laboratories to report findings of *Bartonella* species, to the Department's electronic

disease surveillance system no later than the next work day. The Department proposes to require reporting of *Bartonella* species, to align with the proposed addition of bartonella infection, including "cat scratch fever," to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align with other reporting requirements for clinical laboratories.

Borrelia miyamotoi

The Department proposes to add *Borrelia miyamotoi*, to the new chart and to require clinical laboratories to report findings of *Borrelia miyamotoi*, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Borrelia miyamotoi*, to align with the proposed addition of tickborne diseases, including disease due to Borrelia miyamotoi to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Bourbon virus

The Department proposes to add Bourbon virus, to the new chart and to require clinical laboratories to report findings of Bourbon virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of Bourbon virus, to align with the proposed addition of tickborne diseases, including disease due to Bourbon virus to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Burkholderia mallei and pseudomallei (glanders and melioidosis)

The Department proposes to add *burkholderia mallei* and *pseudomallei* (glanders and melioidosis) to the new chart and to require clinical laboratories to report these agent immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of *burkholderia mallei* and *pseudomallei* (glanders and melioidosis), and to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system, to align with the proposed addition of *burkholderia infection melioidosis (B. pseudomallei) and glanders (B. mallei)* to the reporting requirements for health care providers and facilities in proposed § 27.21a(b). As noted in that section, the Department proposes this amendment due to the potential for these agents to be used as biological weapons.

Cadmium level greater or equal to 5 micrograms per liter (µg/L) of whole blood, or 3 micrograms per gram (µg/g) of creatinine

The Department proposes to add cadmium levels greater or equal to 5 micrograms per liter (µg/L) of whole blood, or 3 micrograms per gram (µg/g) of creatinine to the new chart and to require clinical laboratories to report these levels to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of cadmium levels, to align with the proposed addition of cadmium levels to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Candida auris

The Department proposes to add *Candida auris*, to the new chart and to require clinical laboratories to report findings of *Candida auris*, to the Department's electronic disease

surveillance system no later than the next work day. The Department proposes to require reporting of *Candida auris* to align with the proposed addition of *Candida auris* to the reporting requirements for health care providers and health care facilities. The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Carbapenemase-producing organisms, including carbapenem-resistant Enterobacterales, Pseudomonas species, and Acinetobacter species

The Department proposes to add Carbapenemase-producing organisms (CPO), to the new chart and to require clinical laboratories to report findings of CPO, to the Department's electronic disease surveillance system no later than the next work day. CPO are multi-drug resistant pathogens. CDC. (2023). Carbapenemase-Producing Organisms (CPO). 2023 Case Definition. Retrieved from https://ndc.services.cdc.gov/case-definitions/carbapenemase-producing-organisms-cpo-2023/. Infections from these organisms, including carbapenem-resistant Enterobacterales infections are difficult to treat, and are a cause of outbreaks in health care settings. CDC. (2024). Carbapenem-resistant Enterobacterales (CRE) Infection Control. Retrieved from https://www.cdc.gov/cre/hcp/infection-control/index.html. Due to the difficulty in treating these infections, and the risk for outbreaks, the Department proposes to require clinical laboratories to report CPO so that the Department may take appropriate measures to protect public health and safety. The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Carboxyhemoglobin (COHb) greater or equal to 5% in blood

The Department proposes to add carboxyhemoglobin (COHb) greater or equal to 5% in blood to the new chart and to require clinical laboratories to report COHb greater or equal to 5%

in blood to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of COHb, to align with the proposed addition of COHb to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Chikungunya virus

The Department proposes to add *Chikungunya* virus, to the new chart and to require clinical laboratories to report findings of *Chikungunya* virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Chikungunya* virus, to align with the proposed addition of *Chikungunya* virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Cholinesterase levels, all results

The Department proposes to add cholinesterase levels, all results, to the new chart and to require clinical laboratories to report these levels to the Department's electronic disease surveillance system no later than the next work day. Cholinesterase is an enzyme that is essential for normal functioning of the nervous system. Fishel, F. M. (2021). Pesticides and Cholinesterase. Retrieved from https://journals.flvc.org/edis/article/view/118256/116189. Certain chemical families of pesticides work primarily against pests by interfering with or inhibiting cholinesterase. *Id*. While these chemicals are intended to target pests, they can also be toxic to humans. *Id*. Exposure to the cholinesterase-inhibiting chemicals in pesticides can result from inhalation, ingestion or eye or skin contact during the manufacturing, mixing, or

application of these pesticides. *Id*. The Department proposes to require reporting of cholinesterase levels, to align with the proposed addition of pesticide-related illness and injury to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Clostridium perfringens and Clostridial enterotoxin

The Department proposes to add *Clostridium perfringens* and *Clostridial* enterotoxin to the new chart and to require clinical laboratories to report findings of *Clostridium perfringens* and *Clostridial* enterotoxin, to the Department's electronic disease surveillance system no later than the next work day. *Clostridium perfringens* bacteria are a common cause of food poisoning and is the cause of nearly 1 million foodborne illnesses in the United States each year. CDC. (2024). About *C. perfringens* food poisoning. Retrieved from https://www.cdc.gov/clostridium-perfringens/about/index.html. Outbreaks tend to happen in settings where large groups of people are served, such as hospitals, prisons, school cafeterias, nursing homes and large events with catered food, where keeping food at proper temperatures may be difficult. *Id*. Laboratory testing for *Clostridium perfringens* includes testing for *Clostridial* enterotoxin. CDC. (2024). Laboratory testing for *C. perfringens*. Retrieved from https://www.cdc.gov/clostridium-perfringens/php/laboratories/. The Department proposes to require reporting of *Clostridium perfringens* and *Clostridial* enterotoxin to align with proposed requirements for the reporting of foodborne illnesses by health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Coccidioides species

The Department proposes to add *Coccidioides species*, to the new chart and to require clinical laboratories to report findings of *Coccidioides species*, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Coccidioides species* to align with the proposed addition of *Coccidioidomycosis* to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Coronaviruses, novel, other than COVID-19, including Middle East Respiratory Syndrome virus (MERS-CoV) and the original Severe Acute Respiratory Syndrome virus (SARS-CoV)

The Department proposes to add coronaviruses, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original severe acute respiratory syndrome (SARS), to the new chart. The Department proposes to require clinical laboratories to report findings of coronaviruses, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original severe acute respiratory syndrome (SARS), immediately by telephone, and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of coronaviruses, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original severe acute respiratory syndrome (SARS), and to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system, to align with the proposed addition of coronaviruses, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original severe acute respiratory syndrome (SARS), to the reporting requirements for health care providers and facilities in § 27.21a(b).

Coxiella burnetii (Q fever)

The Department proposes to add *Coxiella burnetii* (Q fever), to the new chart and to require clinical laboratories to report findings of *Coxiella burnetii* (Q fever), to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Coxiella burnetii* (Q fever) to align with the proposed addition of Q fever, acute and chronic, to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Cronobacter species in an infant specimen

The Department proposes to add *Cronobacter species* in an infant specimen, to the new chart and to require clinical laboratories to report findings of *Cronobacter species* in an infant specimen, to the Department's electronic disease surveillance system within 24 hours. The Department proposes to require reporting of *Cronobacter species* and to require reporting within 24 hours to align with the proposed addition of *Cronobacter* infection, infant, to the reporting requirements for health care providers and facilities in § 27.21a(b). As discussed within that section, reporting within 24 hours is necessary so that the Department may properly investigate these cases and take measures to prevent an outbreak of this deadly infection among infants.

Cyclospora cayetanensis (cyclosporiasis)

The Department proposes to add *Cyclospora cayetanensis (cyclosporiasis)*, to the new chart and to require clinical laboratories to report findings of *Cyclospora cayetanensis (cyclosporiasis)*, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of *Cyclospora cayetanensis (cyclosporiasis)* to align with the proposed addition of *cyclosporiasis* to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to

require clinical laboratories to report findings of *Cyclospora cayetanensis (cyclosporiasis)* no later than the next work day to align generally with other clinical laboratory reporting requirements.

Dengue virus

The Department proposes to add dengue virus, to the new chart and to require clinical laboratories to report findings of dengue virus, to the Department's electronic disease surveillance system within the next work day. The Department proposes to require reporting of dengue virus, to align with the proposed addition of dengue virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Eastern equine encephalitis virus

The Department proposes to add Eastern equine encephalitis virus, to the new chart and to require clinical laboratories to report findings of Eastern equine encephalitis virus, to the Department's electronic disease surveillance system within the next work day. The Department proposes to require reporting of Eastern equine encephalitis virus, to align with the proposed addition of Eastern equine encephalitis virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Ehrlichia species

The Department proposes to add *Ehrlichia species*, to the new chart and to require clinical laboratories to report findings of *Ehrlichia species*, to the Department's electronic

disease surveillance system no later than the next work day. The Department proposes to require reporting of *Ehrlichia species* to align with the proposed addition of ehrlichiosis to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require clinical laboratories to report findings of *Ehrlichia species* no later than the next work day to align generally with other clinical laboratory reporting requirements.

Filoviridae species

The Department proposes to add *Flaviviridae species* to the new chart and to require clinical laboratories to report findings of *Flaviviridae species* to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of *Flaviviridae species*, and to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system to align with the proposed addition of filovirus infections to the reporting requirements for health care providers and facilities in § 27.21a(b). As noted in § 27.21a(b), the need to isolate individuals who have filovirus infections necessitates faster reporting.

Foodborne toxins (including mushroom toxins, ciguatera toxins, scombrotoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, staphylococcus enterotoxin, Bacillus cereus toxin, and others)

The Department proposes to add foodborne toxins (including mushroom toxins, ciguatera toxins, scombrotoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, staphylococcus enterotoxin, Bacillus cereus toxin, and others) to the new chart and to require clinical laboratories to report findings of foodborne toxins to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of foodborne toxins to align with the proposed addition of foodborne toxins to the

reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require clinical laboratories to report findings of foodborne toxins no later than the next work day to align generally with other clinical laboratory reporting requirements.

Free-living amoebas, including Acanthamoeba species, Balamuthia mandrillaris, and Naegleria fowleri

The Department proposes to add free-living amebae, including infections caused by *Acanthamoeba* spp., *Balamuthia mandrillaris* and *Naegleria fowleri* to the new chart and to require clinical laboratories to report findings of free-living amebae, including infections caused by *Acanthamoeba* spp., *Balamuthia mandrillaris* and *Naegleria fowleri* to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of free-living amebae, including infections caused by *Acanthamoeba* spp., *Balamuthia mandrillaris* and *Naegleria fowleri* to align with the proposed addition of free-living amebae infections, including infections caused by *Acanthamoeba* spp., *Balamuthia mandrillaris* and *Naegleria fowleri* to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Heartland virus

The Department proposes to add Heartland virus, to the new chart and to require clinical laboratories to report findings of Heartland virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of Heartland virus, to align with the proposed addition of tickborne diseases, including disease due to Heartland virus to the reporting requirements for health care providers and

facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Human metapneumovirus

The Department proposes to add human metapneumovirus to the new chart and to require clinical laboratories to report findings of human metapneumovirus to the Department's electronic disease surveillance system, no later than the next work day. Human metapneumovirus can cause upper and lower respiratory disease in persons of all ages, but especially young children, older adults and people with weakened immune systems. CDC. (2024). About Human Metapneumovirus. Retrieved from https://www.cdc.gov/human-metapneumovirus/about/index.html. The Department proposes to require clinical laboratories, but not health care practitioners or health care facilities to report cases of human metapneumoviruses because generally only severe cases would prompt a provider or facility to send a specimen to the lab for testing and tracking such cases is needed to protect public health, for example, providing education and other measures, in the event that there are a large number of severe cases being reported.

La Crosse encephalitis virus

The Department proposes to add La Crosse encephalitis virus, to the new chart and to require clinical laboratories to report findings of La Crosse encephalitis virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of La Crosse encephalitis virus, to align with the proposed addition of La Crosse encephalitis virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting

no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Marburg virus

The Department proposes to add Marburg virus to the new chart and to require clinical laboratories to report findings of Marburg virus to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of Marburg virus immediately by telephone and within 24 hours to the Department's electronic disease surveillance system to align with the proposed addition of Marburg virus infections to the reporting requirements for health care providers and facilities in § 27.21a(b). As noted in § 27.21a(b), Marburg virus is classified as a Category A agent, which poses a risk to national security because it can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness.

Mercury level greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine or 5 micrograms per gram (µg/g) in hair

The Department proposes to add mercury levels greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine or greater or equal to micrograms per gram (µg/g) in hair to the new chart and to require clinical laboratories to report these levels to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of mercury levels, to align with the proposed addition of mercury levels to the reporting requirements for health care providers and

facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other reporting requirements for clinical laboratories.

Monkeypox (mpox) virus

The Department proposes to add monkeypox (mpox) virus, to the new chart and to require clinical laboratories to report findings of monkeypox (mpox) virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of monkeypox (mpox) virus to align with the proposed addition of monkeypox (mpox) infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require clinical laboratories to report findings of monkeypox (mpox) virus no later than the next work day to align generally with other clinical laboratory reporting requirements.

Nontuberculous mycobacteria isolated from an extrapulmonary site

The Department proposes to add nontuberculous mycobacteria isolated from an extrapulmonary site to the new chart and to require clinical laboratories to report findings of nontuberculous mycobacteria isolated from an extrapulmonary site to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of nontuberculous mycobacteria isolated from an extrapulmonary site to align with the proposed addition of nontuberculous mycobacteria, extrapulmonary infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require clinical laboratories to report findings nontuberculous mycobacteria isolated from an extrapulmonary site no later than the next work day to align generally with other clinical laboratory reporting requirements.

Norovirus

The Department proposes to add norovirus, to the new chart and to require clinical laboratories to report findings of norovirus, to the Department's electronic disease surveillance system no later than the next work day. Norovirus is highly contagious, and is the leading cause of vomiting and diarrhea, and foodborne illness, in the United States. CDC. (2024). About Norovirus. Retrieved from https://www.cdc.gov/norovirus/about/index.html; CDC (2024). How to Prevent Norovirus. Retrieved from https://www.cdc.gov/norovirus/prevention/. The Department proposes to require reporting of norovirus to align with proposed requirements for the reporting of foodborne illnesses by health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with the other reporting requirements for clinical laboratories.

Orthopox virus, not otherwise listed including vaccinia virus

The Department proposes to add orthopox virus, not otherwise listed including vaccinia virus, to the new chart and to require clinical laboratories to report findings of orthopox virus, not otherwise listed including vaccinia virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of orthopox virus, not otherwise listed including vaccinia virus to align with the proposed addition of orthopox virus, not otherwise listed, to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require clinical laboratories to report findings of orthopox virus, not otherwise listed including vaccinia virus no later than the next work day to align generally with other clinical laboratory reporting requirements.

Pandrug-resistant (PDR) organism

The Department proposes to add pandrug-resistant (PDR) organism, to the new chart and to require clinical laboratories to report findings of PDR organism, to the Department's

electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of PDR organism to align with the proposed addition of PDR organism infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require clinical laboratories to report findings of PDR organism no later than the next work day to align generally with other clinical laboratory reporting requirements.

Parainfluenza virus

The Department proposes to add parainfluenza virus to the new chart and to require clinical laboratories to report findings of parainfluenza virus to the Department's electronic disease surveillance system, no later than the next work day. Parainfluenza virus causes symptoms similar to the common cold and commonly causes upper and lower respiratory illness in infants, young children, older adults and those with weakened immune systems. CDC. (2024). About Human Parainfluenza Viruses (HPIVs). Retrieved from https://www.cdc.gov/parainfluenza/about/index.html. The Department proposes to require clinical laboratories, but not health care practitioners or health care facilities to report cases of parainfluenza viruses because generally only severe cases would prompt a provider or facility to send a specimen to the lab for testing and tracking such cases is needed to protect public health, for example, providing education and other measures, in the event that there are a large number of severe cases being reported.

Powassan virus

The Department proposes to add Powassan virus, to the new chart and to require clinical laboratories to report findings of Powassan virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require

reporting of Powassan virus, to align with the proposed addition of Powassan virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

Rhinovirus

The Department proposes to add rhinovirus to the new chart and to require clinical laboratories to report findings of rhinovirus to the Department's electronic disease surveillance system, no later than the next work day. Rhinoviruses are the most frequent cause of the common cold and viral asthma attacks but can cause severe illness in those with weakened immune systems or existing respiratory or cardiac disease. CDC. (2024). About Rhinoviruses. Retrieved from https://www.cdc.gov/rhinoviruses/about/index.html. The Department proposes to require clinical laboratories, but not health care practitioners or health care facilities to report cases of rhinoviruses because generally only severe cases would prompt a provider or facility to send a specimen to the lab for testing and tracking such cases is needed to protect public health, for example, providing education and other measures, in the event that there are a large number of severe cases being reported.

Ricin

The Department proposes to add ricin to the new chart and to require clinical laboratories to report these agent immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of ricin and to require reporting immediately by telephone and within 24 hours to the Department's electronic disease surveillance system, to align with the proposed addition of ricin to the reporting requirements for health care providers and facilities in proposed § 27.21a(b). As noted

in that section, the Department proposes this amendment due to the potential for these agents to be used as biological weapons.

St. Louis encephalitis virus

The Department proposes to add St. Louis encephalitis virus, to the new chart and to require clinical laboratories to report findings of St. Louis encephalitis virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of St. Louis encephalitis virus, to align with the proposed addition of St. Louis encephalitis virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

SARS-CoV-2 (COVID-19)

The Department proposes to add SARS-CoV-2 (COVID-19) to the new chart and to require clinical laboratories to report findings of SARS-CoV-2 (COVID-19) to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of SARS-CoV-2 (COVID-19) to align with the proposed addition of SARS-CoV-2 (COVID-19) to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

Smallpox virus

The Department proposes to add smallpox virus to the new chart and to require clinical laboratories to report findings of smallpox virus to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of smallpox virus immediately by telephone and within 24 hours to

the Department's electronic disease surveillance system to align with the requirement for health care providers and facilities in § 27.21a(b) to report smallpox virus. As noted in § 27.21a(b), smallpox is classified as a Category A agent, which poses a risk to national security because it can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness.

Streptococcus pyogenes, Group A, recovered from any normally sterile body site

The Department proposes to add *streptococcus pyogenes*, group A, recovered from any normally sterile body site to the new chart and to require clinical laboratories to report findings of streptococcus pyogenes, group A, recovered from any normally sterile body site to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of streptococcus pyogenes, group A, recovered from any normally sterile body site, to align with the proposed addition of *Streptococcal* invasive disease (group A), with organism identified in a normally sterile site to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

West Nile Virus

The Department proposes to add West Nile virus, to the new chart and to require clinical laboratories to report findings of West Nile virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of West Nile virus, to align with the proposed addition of West Nile virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The

Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

Yellow fever virus

The Department proposes to add yellow fever virus, to the new chart and to require clinical laboratories to report findings of yellow fever virus to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system . The Department proposes to require reporting of yellow fever virus, to align with the proposed addition of yellow fever virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b).

Yersinia enterocolitica

The Department proposes to add yersinia enterocolitica, to the new chart and to require clinical laboratories to report findings of yersinia enterocolitica, to the Department's electronic disease surveillance system no later than the next work day. Both yersinia enterocolitica and yersinia pseudotuberculosis can cause yersiniosis. CDC. (2024). About *Yersinia* Infection. Retrieved from https://www.cdc.gov/yersinia/about/index.html. The Department proposes to require reporting of yersinia enterocolitica, to align with the proposed addition of yersiniosis to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

Yersinia pseudotuberculosis

The Department proposes to add yersinia pseudotuberculosis, to the new chart and to require clinical laboratories to report findings of yersinia pseudotuberculosis, to the Department's electronic disease surveillance system no later than the next work day. CDC.

(2024). About *Yersinia* Infection. Retrieved from https://www.cdc.gov/yersinia/about/index.html. The Department proposes to require reporting of yersinia pseudotuberculosis, to align with the proposed addition of yersiniosis to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting no later than the next work day to align generally with other clinical laboratory reporting requirements.

Zaire Ebolavirus

The Department proposes to add Zaire ebolavirus to the new chart and to require clinical laboratories to report findings of Zaire ebolavirus to the Department immediately by telephone and within 24 hours to the Department's electronic disease surveillance system. The Department proposes to require reporting of Zaire ebolavirus immediately by telephone and within 24 hours to the Department's electronic disease surveillance system to align with the proposed addition of Ebola infection to the reporting requirements for health care providers and facilities in § 27.21a(b). As noted in § 27.21a(b), Ebola is classified as a Category A agent, which poses a risk to national security because it can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness.

Zika virus

The Department proposes to add Zika virus, to the new chart and to require clinical laboratories to report findings of Zika virus, to the Department's electronic disease surveillance system no later than the next work day. The Department proposes to require reporting of Zika virus, to align with the proposed addition of Zika virus infection to the reporting requirements for health care providers and facilities in § 27.21a(b). The Department proposes to require reporting

no later than the next work day to align generally with other clinical laboratory reporting requirements.

Subsection (c)

The Department proposes to delete "except as provided in subsection (d)" from the beginning of this section. As discussed below, the Department proposes to delete subsection (d). Therefore, this reference is no longer needed.

In paragraph (1), the Department proposes to replace the word "age" with the words "date of birth" and to add gender, race and ethnicity to the information that clinical laboratories are required to report. The Department proposes to require this data to identify health equity issues, determine vulnerable populations, for disease surveillance to determine affected groups, and allocation of resources to prevent and control disease. In paragraph (3), the Department proposes to add "venous" and "capillary" to the types of specimen to be identified by a clinical laboratory in its report as the source of the specimen will impact how to interpret results. For example, lead test results are interpreted differently depending on whether the source is venous or capillary. The Department also proposes to add the word "or" between the words "CSF" and "wound" for grammatical reasons.

The Department also proposes to add "and the location of the body that the specimen was collected from" to this reporting requirement. For sexual transmitted diseases, sites of contact that are needed to be tested are dependent on sex of the individual and their sexual activity. CDC. (2021). Screening Recommendations and Considerations Referenced in Treatment Guidelines and Original Source. Retrieved from https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm. Additionally, testing sites may be recommended for certain tests and reporting the site provides affirmation that the result was completed

properly. For example, for *candida auris* colonization screening, it is recommended that a composite swab of the patient's bilateral axilla and groin be taken. CDC. (April 24, 2024). Screening Recommendations for Healthcare Facilities. Retrieved from https://www.cdc.gov/candida-auris/hcp/screening-hcp/index.html.

In paragraph (7), the Department proposes to replace "the physician for whom the examination or test was performed" with "ordering health care practitioner and the facility that ordered the test." The Department proposes the amendment from "physician" to "health care practitioner" for consistency in use of terminology throughout the proposed regulations. The Department proposes the addition of "facility" for clarity as the "ordering health care practitioner" may work in more than one facility.

The Department proposes to add new requirements to paragraphs (7.1) through (7.3). In paragraph (7.1), the Department proposes to require a clinical laboratory to identify the "name and address" of the employer for persons who are occupationally exposed to assist in disease investigations for these cases by linking them to the employer. In paragraph (7.2), the Department proposes to require a clinical laboratory to report the "pregnancy status, of the person from whom the specimen was obtained, if known" as treatment in cases of pregnancy can be different. For example, Zika will impact the fetus, and pregnant individuals with some sexually transmitted diseases can only be treated with certain medications. In paragraph (7.3), the Department proposes to require a clinical laboratory to identify "the name of the clinical laboratory that performed the test" to aid in disease investigations and cases where there are issues with laboratory results, such as false positives, delayed reporting, or incomplete reporting.

Subsection (d)

The Department proposes to delete this subsection. As mentioned previously, specific requirements for the reporting of cases in newborns will be addressed in proposed amendments to § 27.30. In addition, specific reporting requirements for cancer exist currently in § 27.31, which the Department proposes to amend, as described below. Because these reporting requirements will be addressed elsewhere, it is not necessary to retain them in this subsection.

Subsection (e)

The Department proposes to delete this subsection. Submission requirements for isolates, including salmonella and shigella, are addressed in new, proposed subsection (j)(10) and (11), described below. Because these reporting requirements will be addressed elsewhere, it is not necessary to retain them in this subsection.

Subsection (f)

The Department proposes to delete this subsection. Submission requirements for isolates, including Neisseria meningitidis obtained from a normally sterile site, are addressed in new, proposed subsection (j)(7), described below. Because these reporting requirements will be addressed elsewhere, it is not necessary to retain them in this subsection.

Subsection (g)

The Department proposes to delete this subsection. Submission requirements for isolates, including enterohemorrhagic E. coli, are addressed in new, proposed subsection (j)(12), described below. Because these reporting requirements will be addressed elsewhere, it is not necessary to retain them in this subsection.

Subsection (h)

The Department proposes to delete this subsection. Submission requirements for isolates, including Haemophilus influenzae obtained from a normally sterile site, are addressed in new,

proposed subsection (j)(4), described below. Because these reporting requirements will be addressed elsewhere, it is not necessary to retain them in this subsection.

Subsection (i)

The Department proposes to delete this subsection. The Department does not have the authority to authorize changes in the requirements for submission of isolates through publication of a notice in the *Pennsylvania Bulletin*.

Subsection (j)

This proposed subsection is new. As noted above, clinical laboratories are required by existing subsections (e) through (h) to submit certain named isolates. The Department proposes to add these isolates to this new subsection in addition to several other isolates, while retaining the requirement for submission within 5 work days of identification. The Department proposes to place these requirements together in the same subsection, in alphabetical order, to make it easier for the regulated community to locate them. The new, proposed isolates are needed for the identified diseases and conditions for cluster or outbreak identification, understanding of genetic changes in the circulating organisms or agencies, and to determine the availability of treatments or vaccines.

Specifically, in proposed paragraph (1), the Department proposes to require submission of isolates for *candida auris*, as some isolates of *candida auris* are resistant to one or more classes of antifungal drugs. Du, H. *et al*. (2020). "*Candida auris*: Epidemiology, Biology, Antifungal Resistance, and Virulence." *PLoS Pathogens*, 16(10). Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC7581363/. In proposed paragraph (2), the Department proposes to require submission of isolates for Carbapenemase-producing organisms. Carbapenemase-producing organisms are multi-drug resistant, and submission of the isolate aids

in identifying treatment implications. Tamma, P. and Simner, P. (2018). "Phenotypic Detection of Carbapenemase-Producing Organisms from Clinical Isolates." *Journal of Clinical Microbiology*, 56(11). Retrieved from https://pubmed.ncbi.nlm.nih.gov/30158194/. In proposed paragraph (3), the Department proposes to require submission of isolates for corynebacterium diphtheria. In order to confirm a diagnosis of corynebacterium, the isolate must be toxin producing. CDC. (2024). Laboratory Testing for Diphtheria. Retrieved from https://www.cdc.gov/diphtheria/php/laboratories/index.html.

In proposed paragraph (4), the Department proposes to require submission of isolates for *Haemophilus influenzae*. As noted previously, clinical laboratories are already required under existing subsection (h) to submit isolates for *Haemophilus influenzae*. In proposed paragraph (5), the Department proposes to require submission of isolates for *Listeria monocytogenes*, or other pathogenic *Listeria* species. *Listeria* is a foodborne disease, and the isolates help identify whether a case is associated with an outbreak and will help to identify the source of the outbreak. CDC. (2025). *Listeria* Infection (Listeriosis). Retrieved from https://www.cdc.gov/listeria/php/surveillance/surveillance.html. In proposed paragraph (6), the Department proposes to require submission of isolates for *mycobacterium tuberculosis*, or tuberculosis complex, including *bovis* and *bovis* BCG (all sites). The isolates will identify drug resistance and effective treatment. CDC. (2024). Tuberculosis Laboratories. Retrieved from https://www.cdc.gov/tb/php/laboratory-information/index.html. In proposed paragraph (7), the Department proposes to require submission of isolates for *Neisseria meningitidis*, recovered from any normally sterile body site. As noted previously, clinical laboratories are already required under existing subsection (f) to submit isolates for Neisseria *meningitidis*, recovered from any normally sterile body site.

In proposed paragraph (8), the Department proposes to require submission of isolates for coronavirus infection, novel, other than COVID-19, including MERS-CoV and SARS-CoV. The isolates help with understanding of current vaccines, treatments, diagnostics, and risk to public health. CDC. (2024). CDC's Role in Tracking Variants. Retrieved from https://www.cdc.gov/covid/php/variants/index.html. In proposed paragraph (9), the Department proposes to require submission of isolates for polio virus, positive viral cultures. Isolates are the most sensitive method to diagnose poliovirus infection. CDC. (2024). Laboratory Testing for Poliovirus. Retrieved from https://www.cdc.gov/polio/php/laboratories/index.html. In proposed paragraph (10), the Department proposes to require submission of isolates for *salmonella*, all types including Typhi and Paratyphi. As noted previously, clinical laboratories are already required under existing subsection (e) to submit isolates for salmonella. The Department proposes to add "all types including Typhi and Paratyphi" to clarify that isolates for all types are to be submitted. In proposed paragraph (11), the Department proposes to require submission of isolates for shigella species. As noted previously, clinical laboratories are already required under existing subsection (e) to submit isolates for shigella. The Department proposes to add "species" to clarify the etiologic agent that the laboratories would be testing for.

In proposed paragraph (12), the Department proposes to require submission of isolates for Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC). As noted previously, clinical laboratories are already required under existing subsection (g) to submit isolates for enterohemorrhagic E. coli. As noted elsewhere, the Department proposes to replace "enterohemorrhagic E. coli" with "Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC)" as this is the more commonly used and recognized term for the subset of *E. coli* bacteria that produce Shiga toxin. In proposed paragraph (13), the Department proposes to require submission of

isolates for vaccinia virus. Vaccinia virus isolates help to characterize an outbreak and virulence of the specific virus. Abrahoa, SJ, et al. (2015). "Outbreak of Severe Zoonotic Vaccinia Virus Infection, Southeastern Brazil." *Emerging Infectious Diseases*, 21(4):695-698. Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC4378504/.

In proposed paragraph (14), the Department proposes to require submission of isolates for *Vibrio* species, including *Vibrio cholerae*. *Vibrio* species can be caused by raw or undercooked seafood and is detected through isolates of the bacteria. CDC. (2024). Clinical Overview of Vibriosis. Retrieved from https://www.cdc.gov/vibrio/hcp/clinical-overview/index.html. In proposed paragraph (15), the Department proposes to require submission of isolates for other cultures or specimens as requested by the Department. Antimicrobial resistance, which impacts treatment, is emerging and could impact the isolates needed in the future for a public health response. Gajic, I., et al. (2022). "Antimicrobial Susceptibility Testing: A Comprehensive Review of Currently Used Methods." *Antibiotics (Basel)*, 11(4):427. Retrieved from https://pubmed.ncbi.nlm.nih.gov/35453179/.

Subsection (k)

This proposed section is new. The Department proposes to require a clinical laboratory to report reflex culture results for the organisms listed in proposed subsection (j), whether positive or negative. Reflex culture results can ensure appropriate treatment and prevent the unnecessary use of antibiotics. Ourani, M, et al. (2021). "Evaluation of Evidence-Based Urinalysis Reflex to Culture Criteria: Impact on Reducing Antimicrobial Usage." *International Journal of Infectious Disease*, 102: 40-44. Retrieved from https://pubmed.ncbi.nlm.nih.gov/33011278/. Unnecessary use of antibiotics contributes to antimicrobial resistance or a germs ability to defeat drugs designed to kill them. CDC. (2024).

Antibiotic Use and Antimicrobial Resistance Facts. Retrieved from https://www.cdc.gov/antibiotic-use/data-research/facts-stats/index.html.

Subsection (l)

This proposed section is new. The Department proposes to require a clinical laboratory to contact the Department's Bureau of Laboratories immediately by telephone if it suspects one of the select agents and toxins listed in paragraphs (1) through (12) in a specimen or culture, and to immediately submit the specimen or isolate to the Bureau or another laboratory designated by the Bureau. The select agents and toxins that the Department proposes to include in paragraphs (1) through (12) are as follows: *Bacillus anthracis* or *Bacillus* cereus Biovar *anthracis*; *Brucella* species; *Burkholderia mallei*; *Burkholderia pseudomallei*; *Clostridium botulinum*; Ebola virus; Filovirus, not otherwise specified; *Francisella tularensis*; Marburg virus; ricin; variola virus; and *Yersinia pestis*. These select agents and toxins are all designated by the CDC as either Category A or Category B select agents and toxins, which either pose a risk to national security or have the potential to be used as biological weapons and require special handling. The Department therefore proposes to require clinical laboratories to contact the Department's Bureau of Laboratories if they suspect that one of these select agents and toxins are in a specimen or culture, and to immediately submit the specimen or isolate to the Bureau or a designated laboratory for testing.

§ 27.22a. Reporting of select agents and toxins.

This proposed section is new. The Department proposes to implement laboratory requirements for a detected release, exposure, loss or theft of a select agent or toxin. As noted in proposed § 27.1, a select agent or toxin is "biological material that has the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products,

as determined by the DHHS and USDA under 7 CFR 331.3, 9 CFR 121.3, 9 CFR 121.4, and 42 CFR 73.3. A full list of select agents and toxins identified by the DHHS and USDA is located on the Federal Select Agent Program's website. *See* Federal Select Agent Program. (2023). Select Agents and Toxins List. Retrieved from https://www.selectagents.gov/sat/list.htm.

Subsection (a)

The Department proposes to require laboratories that possess, use or transfer select agents or toxins to report, to the Department's Bureau of Laboratories, a detected release, exposure, loss or theft of a select agent or toxin. The Department proposes to require the lab to report within one hour, via telephone call or email, followed by submission of a written report within 7 days of the incident. The Department proposes in paragraphs (1) through (8) for the written report to include the following: name, physical address, telephone number and address of the laboratory; the name, physical address, telephone number and email address of the officer or person in charge of the laboratory; the name of the select agent or toxin; the names of persons potentially exposed to the select agent or toxin; the quantity of the select agent or toxin suspected or known to have been release, lost or stolen; a description of the incident, including the time and location that the release, exposure, loss or theft occurred; an assessment of the severity of the incident; and other information as requested by the Department.

The Federal Select Agent Program is primarily responsible for tracking select agents and toxins, and requires immediate reporting via telephone, email, or facsimile of an incident. However, the Department should also be informed so that a local response can be mobilized to find, contain and otherwise protect those at risk of exposure, or treat individuals who have already been exposed. *See* Federal Select Agent Program. (2020). APHIS/CDC Form 3 – Incident Notification and Reporting. Retrieved from

https://www.selectagents.gov/resources/docs/APHISCDC-Form-3-Incident-Notification-and-Reporting.pdf. The Department's proposed timeframe for telephone or email reporting takes into consideration a laboratory's requirement to speak with the Federal Select Agent Program first, while ensuring that a local response can be implemented within a sufficient timeframe to protect the health and safety of those in the vicinity of the incident. The information that the Department proposes to request in the written report aligns with information that the laboratory will have already reported to the Federal Select Agent Program. This information will aid the Department in assisting appropriately scaling the response effort on a local level, assisting with containment and isolation efforts, appropriately scale response effort on a local level, and coordinating with health care providers and facilities to ensure that persons exposed are appropriately treated and isolated, if necessary. The inclusion of "other information as requested by the Department" is intended as a catch-all if the Department needs additional information to assist with these efforts, such as if exposed persons can continue to impact public health, and, if so, where they have been and where they will be receiving treatment. This catch-all will allow the Department to collect information necessary to prevent or control the impact of the release of the select agent or toxin on the public.

Subsection (b)

The Department proposes to define a laboratory for the purposes of this section as including a commercial, research or clinical laboratory. The Department intends for all laboratories, not just clinical laboratories, that have possession of a select agent or toxin with a detected release, exposure, loss or theft, notify the Department as required by proposed subsection (a). Select agents and toxins, in many cases, pose a risk to national security and can be used as biological weapons. Therefore, it is crucial that the Department be made aware of any

release, exposure, loss or theft of a select agent or toxin, regardless of the type of laboratory that possesses, uses or transfers such select agents and toxins.

§ 27.23. Reporting of cases by persons in charge of child care group settings.

The Department proposes to replace "other than health care practitioners, health care facilities, veterinarians or laboratories" with "in charge of child care group settings" in the title of this section. This proposed amendment adds clarity, and better reflects the substance of this section, which with proposed amendments will apply only to persons in charge of child care group settings. The Department proposes to delete outdated requirements for reporting of cases by "institutions maintaining dormitories and living rooms." The Department also proposes to delate requirements for reporting of cases by "orphanages." Orphanages are defunct institutions, replaced by the foster-care system in the late 20th century, and no longer need to be included in this section. *See* Spence, V. (2023). Do Orphanages Still Exist in America? A Brief History of Orphanages in the United States. Retrieved from https://adoption.com/do-orphanages-still-exist/.

The Department proposes to delete language excluding the reporting of cancer, AIDS, CD4 T-lymphocyte counts and percentages, HIV test results or perinatal exposure of a newborn to HIV, HIV viral load results, including detectable and undetectable viral load results, and HIV genotype results. As noted previously, reporting requirements for these diseases and conditions are addressed elsewhere within the regulations, specifically in §§ 27.31 and 27.32a. The Department proposes to replace the language requiring reporting of cases by persons in "child care group settings" with the following, "to prevent a public health emergency or during a public health emergency, the Department may require that persons in charge of child care group settings report suspected or known cases of the diseases, infections or conditions listed in § 27.21a." Because health care providers and facilities are already reporting the diseases, conditions and

infections listed in § 27.21a, it is not necessary for a person in charge of a child care group setting to report them separately. In addition, if a child care group setting was involved in a case reported by a health care provider or facility, the Department would be able to trace it back to the child care group setting during an investigation. The Department proposes, however, to retain language in this section pertaining to its authority to request, when necessary, that persons in charge of child care group settings report cases to prevent a public health emergency or during a public health emergency.

During stakeholder engagement, some stakeholders requested that the Department amend this section to definitively require reporting of suspected or known cases of the diseases, infections or conditions, listed in § 27.21a, during a public health emergency or to prevent one. The Department, after considering current and past practices, chose to not adopt the suggestion as this would require the Department to ask every child care group center to submit identified reportable diseases during a public health emergency, which could be a logistical burden and result in unnecessary data collection. However, the Department chose to strengthen the language after hearing the suggestion, by giving the Department the ability to require child care group settings to report cases, when the Department deems it necessary, during a public health emergency instead of merely requesting it from them. Granting a child care group setting discretionary authority to require such reporting in select circumstances negates the aforementioned risk and represents the least burdensome acceptable alternative.

It was also suggested by some stakeholders to include reporting of pinworm (enterobiasis) in this section by persons in charge of child care group settings. After consideration, the Department chose not to add pinworm to this section as pinworm is not a nationally notifiable disease identified by the CDC, and after reviewing other states, it does not

appear to be a common requirement at the state level either. Pinworm is relatively common and treatable. The main public health risk would be mostly in an institutional setting (health care, prisons, etc.), which would be captured through requirements elsewhere in the proposed regulations, should an outbreak occur.

§ 27.24a. Reporting of cases by veterinarians.

The Department proposes to remove the requirement that a veterinarian report cases only if the veterinarian treats or examines an animal that the veterinarian suspects of having one of the diseases listed in § 27.35(a) (relating to reporting of cases of disease in animals). The Pennsylvania Department of Agriculture has extensive reporting requirements for veterinarians. *See* Pennsylvania Animal Diagnostic Laboratory System (PADLS). (2017). Reportable Disease List. Retrieved from http://padls.agriculture.pa.gov/InnerPages/Reportable_Diseases.html. To eliminate duplicate reporting between the Department and the Department of Agriculture, the Department proposes to only require veterinarians to report certain disease, infections and conditions to the Department that may impact humans. Specifically, the Department proposes to require veterinarians to report the following diseases, infections or conditions in animals: La Crosse encephalitis virus; novel influenza A; St. Louis encephalitis virus; yellow fever virus; and an outbreak, public health emergency or unusual disease, infection or condition. The Department proposes to require reporting of these diseases, infections and conditions, which are not currently reportable to the Department of Agriculture, to aid in tracking where these infections are occurring to take appropriate measures to protect public health if, for example, there is an uptick in mosquito-borne illness in a certain area of this Commonwealth.

The Department proposes to require reporting of La Crosse encephalitis virus, novel influenza A, St. Louis encephalitis virus and yellow fever virus by telephone within 5 work days.

The Department proposes reporting by telephone because veterinarians generally do not have access to the Department's electronic disease surveillance system. The Department proposes reporting within 5 work days in order to engage in mitigation measures to prevent additional spread of the disease within animals, such as vector control, depopulation, animal quarantine, and surveillance. Reducing spread within animals will help prevent the spread to humans. CDC. (2024). About One Health. Retrieved from https://www.cdc.gov/one-health/about/index.html. The Department proposes to require reporting of an outbreak, public health emergency or unusual disease, infection or condition in the time and manner set forth in § 27.3 (relating to reporting of outbreaks, public health emergencies and unusual diseases, infections and conditions). The Department proposes to align veterinarian reporting of animals with the reporting of outbreaks, public health emergencies and unusual diseases, infections and conditions for humans as the mitigation measures to prevent additional spread, as discussed above, must occur faster when there are multiple cases and there is an outbreak.

§ 27.29. Reporting for special research projects.

The Department proposes to delete this section. The Board no longer reviews or approves research studies. Instead, the Department's Institutional Review Board is tasked with ensuring the protection of human subjects in research studies.

Diseases and Conditions Requiring Special Reporting

§ 27.30. Reporting of cases of certain diseases in the newborn child.

The Department proposes to replace the language in this section, which currently requires reporting of specific cases of diseases in newborns, with new language, as follows.

Subsection (a)

The Department proposes to require health care practitioners, health care facilities and clinical laboratories to report newborn diseases and conditions to the Department's Division of Newborn Screening and Genetics, Bureau of Family Health in accordance with the requirements of the Newborn Child Testing Act (35 P.S. §§ 621—625), and its regulations. This regulation exists at 28 Pa. Code, Chapter 28. The Newborn Child Testing Act established a program within the Department to provide for screening tests of newborn children and follow-up services for certain diseases and conditions in the newborn child. *See* 35 P.S. § 621.23. The Department proposes to amend existing § 27.30 to eliminate specifying certain diseases and conditions and to instead defer to the Newborn Child Testing Act with a cross-reference to that act, and its' regulations, because the Department has the authority, with the approval of the Newborn Screening and Follow-up Technical Advisory Board, to make changes to the reportable list of diseases and conditions under that act through publication in the *Pennsylvania Bulletin*, rendering the list subject to change. *See* 35 P.S. § 623(d).

Subsection (b)

The Department proposes to add language indicating that the Department will maintain an updated list of reportable newborn disease and conditions on its website. Section 3(d) of the Newborn Child Testing Act (35 P.S. § 623(d)) permits the Department, with the approval of the Newborn Screening and Follow-Up Technical Advisory Board, and after public comment, to make changes to the lists of disorders for which screening is required, by transmitting a notice to the Legislative Reference Bureau for publication in the *Pennsylvania Bulletin*. The Department will update the regulations as new diseases are added. However, providing a current, up-to-date list on the Department's website, and directing the regulated community to the website through regulation, will ensure that the regulated community has the most up-to-date list of requirements,

while future amendments to the regulations are going through the regulatory process. *See* Newborn Screening Mandated Screening Panel and Supplemental Mandated Screening Panel. (2024). Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/programs/infant-and-children-health/PA%20Newborn%20Screening%20Condition%20List.pdf.

Subsection (c)

The Department proposes to require cases of Neonatal Abstinence Syndrome (NAS) to be reported to the Department's Division of Newborn Screening and Genetics, Bureau of Family Health. NAS became a reportable condition in 2018 when the opioid epidemic was declared a statewide disaster emergency. The emergency declaration has since expired, but hospitals and birthing centers continue to report cases of NAS to the Department. The Department proposes to require, under its authority in the Act, through regulation, that this reporting continue. The purpose of this reporting is to acquire deidentified aggregate data to describe the burden of NAS in this Commonwealth, to identify high incidence areas within this Commonwealth for the purpose of targeted intervention, and to reduce statewide incidence rates of NAS. Cases of NAS are identified utilizing the case definition for NAS developed by the Council of State and Territorial Epidemiologists (CSTE), with subject matter support and review from the CDC. CSTE. (2023). CSTE Neonatal Syndrome Surveillance Implementation Guide. Retrieved from https://nas.cste.org.

§ 27.31. Reporting of cases of cancer and brain-related tumors.

The Department proposes to add "and brain-related tumors" to the title of this section to account for proposed amendments throughout this section to include reporting requirements for "brain-related tumors" as explained below.

Subsection (a)

The Department proposes to replace "for cancer to cancer to patients" with "to patients for cancer or brain-related tumors" and to add "or brain-related tumor" after the words "each case of cancer" in this subsection. The Department also proposes to replace the words "Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and Research" with "Department's electronic cancer registry." The Department proposes these amendments to align with current practice, as well as current law. The Pennsylvania Cancer Control, Prevention and Research Act (35 P.S. § 5636), enacted in this Commonwealth in 1980, requires reporting of cancer cases to the Department. The United States Cancer Registries Amendment Act was thereafter enacted in 1992 to provide funding and technical assistance to statewide cancer registries. *See* 42 U.S.C. §§ 280e—280e-5. The Federal law was amended in 2002 by the Benign Brain Tumor Cancer Registries Amendment Act (Pub. L. No. 107-260) to include requirements for reporting brain-related tumors. Reporting of cancer and brain-related tumors is currently done through the Pennsylvania Cancer Registry, housed within the Department. As noted previously, the Department proposes to add a definition for "brain-related tumor" in § 27.1 to align with theses updates in the law.

Subsection (b)

The Department proposes to delete the word "cancer" before the word "patients" in the first and second sentences of this subsection and before the word "case" in the first sentence for grammatical purposes. The inclusion of the words "cancer" before "patients" and "case" is duplicative and unnecessary. The Department proposes to add the words "or brain-related tumors" after the word "cancer" in the first sentence and "for cancer or brain-related tumors" after the word "patients" in the second sentence. The Department also proposes to replace the

reference to "in a format prescribed by the Department" with "Department's electronic cancer registry." The Department proposes these amendments for consistency and alignment with the law as described in proposed subsection (a), and elsewhere in this preamble. Finally, the Department proposes to expand the time for reporting from within "5 work days" of diagnosis to "180 days" of diagnosis. The Department proposes this amendment to align reporting requirements for health care practitioners with the timeframe in subsection (a) that already exists for reporting by hospitals, clinical laboratories, and other health care facilities.

Subsection (c)

The Department proposes to replace the term "physicians and surgeons" with the term "health care practitioners" for consistency in the use of this term throughout the regulations. The Department proposes to replace the term "nursing homes" with the term "long-term care nursing facilities" for consistency. Nursing homes are referred to elsewhere within the regulations as "long-term care nursing facilities." *See*, *e.g.*, the definition of "health care facility" in proposed § 27.1. Finally, the Department proposes to add "or brain-related tumors" to all instances of the word "cancer" for consistency with the proposed inclusion of brain-related tumors to the Department's reporting requirements, as described in proposed subsection (a), and elsewhere in this preamble.

Subsection (e)

The Department proposes to delete subsection (e). As mentioned in subsection (a), the Department proposes to require that cases of cancer and brain-related tumors be reported to the Department's electronic cancer registry to reflect current practice in the reporting of cases to the Pennsylvania Cancer Registry.

§ 27.32b. Confidential and anonymous testing.

The Department proposes one amendment to this section. In subsection (b), the Department proposes to delete the words "counseling and" because those words are no longer on the HIV testing report form utilized by the Department. *See* Attachment A.

§ 27.32c. Partner services relating to HIV and AIDS.

The Department proposes one amendment to this section. In subsection (b), the Department proposes to add "partner elicitation" to the list of items that are included in partner services provided by the Department or local health department. Partner elicitation is already being conducted by the Department and involves obtaining from a person infected with HIV or AIDS sufficient information about exposure through sex and needle-sharing so that partners can be located and notified. Macke, BA and Maher, JE. (1999). Database of Abstracts of Reviews of Effects (DARE): Quality-assessed Reviews. "Partner Notification in the United States: An Evidence-Based Review." Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK67682/. Partner elicitation aids in locating and notifying partners of exposure, and medical evaluation of partners including laboratory testing, treatment, education, and referral to services, and therefore is an essential part of providing partner services. *Id*.

§ 27.32d. Department authority to require complete reporting.

The Department proposes to replace the word "will" with "or local health department shall" in the first sentence as local health departments have primary jurisdiction for disease investigations within their jurisdiction. The proposed amendment from the word "will" to the mandatory word "shall" makes it clear that health care practitioners, hospitals, persons providing HIV services and person in charge of entities providing HIV services, making AIDS diagnoses, or who receive or provide test results are required to provide the Department or local health department with access and the ability to review patient records. The Department also proposes

to add “or local health department” after the word “Department” in the second sentence to make it clear that the purpose of this access and review is to enable the Department or local health department to conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays and to investigate other reporting problems.

§ 27.32e. Record audits.

The Department proposes to add “or local health department” to make it clear that either the Department or local health department may conduct record audits for the purpose of obtaining information that will allow the Department or local health department to complete case reports for HIV, CD4 T-lymphocytes, and viral load and HIV genotyping; that the Department or local health department may audit records going back to January 1, 2000, for this purpose; and that the Department or local health department may require special reports of persons or entities required to report under this chapter to ensure compliance with this chapter.

§ 27.33. Reporting cases of sexually transmitted disease.

The Department proposes to delete this section because it is duplicative of existing requirements in §§ 27.21a and 27.22, as well as the proposed addition of these cases in the new charts in §§ 27.21a and 27.22. The proposed inclusion of sexually transmitted diseases in the new charts for health care practitioners and facilities, and laboratories, will eliminate the need to have a separate section addressing the reporting requirements for these diseases, and will make it easier for the regulated community to determine what diseases need to be reported, when and how.

§ 27.33a. Reporting treatment for sexually transmitted diseases and tuberculosis.

This proposed section is new.

Subsection (a)

The Department proposes to require that health care practitioners and health care facilities report treatment provided to all suspected or confirmed cases of tuberculosis as well as the following sexually transmitted diseases: chancroid; chlamydia trachomatis infection; gonococcal infection; granuloma inguinale; lymphogranuloma venereum; and syphilis. Practitioners and facilities are already required to report these diseases in existing §§ 27.21a and 27.22 and will continue to be required to report them under the proposed amendments to those sections. The Department proposes, in this subsection, to require that treatment for these diseases be reported through the Department's electronic disease surveillance system or to the local health department. The reporting of treatment will assist the Department in determining whether a new report of tuberculosis or sexually transmitted disease in a patient is entirely new or associated with a previous report. This information will help the Department to determine whether cases can be attributed to a new outbreak or cluster as well as determine the appropriate public health response.

Subsection (b)

The Department proposes that the treatment for tuberculosis and the sexually transmitted diseases, listed in subsection (a), be reported within 5 work days and shall include the date of treatment, medications prescribed or administered, and the dose of medication. Timely and appropriate treatment is crucial to prevent the spread of infection and to ensure that patients do not suffer any long-term effects of untimely or improper treatment.

Subsection (c)

The Department proposes to require a health care practitioner or health care facility to provide, upon request, records related to tuberculosis evaluation and treatment of a patient by facsimile or other means acceptable to the Department within 48 hours. Most tuberculosis cases

are treated by the Department. The Department has encountered issues when individuals are not treated by the Department, and therefore proposes this requirement to ensure that individuals with tuberculosis are receiving appropriate treatment. The Department proposes to accept other means for reporting as an alternative to securely transmit the records to the Department. The health care practitioner or health care facility will be expected to contact the Department's Bureau of Communicable Disease to inquire about available alternative methods of reporting.

§ 27.33b. Reporting of animal bites, scratches or contamination of open wounds or mucous membranes.

This proposed section is new. The Department proposes to require a health care practitioner or a health care facility to report human exposure or suspected human exposure to saliva or neural tissue from a mammal through a bite, scratch or contamination of an open wound or mucous membrane to the local health department serving the geographical area in which the case is identified or the Department's district office or state health center in that region. Existing § 27.21a(b)(1) requires a health care practitioner or health care facility to report animal bites within 24 hours after being identified by symptoms, appearance or diagnosis. The Department proposes to move the requirement for reporting of animal bites to its own section and to clarify that the requirement pertains to bites from mammals as the Department is primarily concerned only with exposure or possible exposure to diseases, conditions or infections that can be transferred from mammals, other than humans, to humans. The Department proposes to also require that practitioners or facilities report mammal scratches or contamination of open wounds or mucous membranes. The Department proposes this expansion due to the risk of rabies, a fatal but preventable viral disease that can be spread to people and pets through the bites and scratches of an infected mammal. CDC. (2024). About Rabies. Retrieved from

https://www.cdc.gov/rabies/about/index.html. Immediate medical attention following a suspected rabies exposure is critical. *Id*.

The Department proposes to retain the existing requirement for reporting within 24 hours and to apply it to bites, scratches and contamination of open wounds or mucous membranes. The Department proposes to require reporting by facsimile or by other means acceptable to the Department to accommodate reporting from emergency departments in hospitals that may not have access to electronic reporting. This reflects the current practice for reporting by emergency departments as well. The Department proposes to accept other means for reporting as an alternative to securely transmit the records to the Department. The health care practitioner or health care facility will be expected to contact the Department's Bureau of Community Health Systems to inquire about available, alternative methods of reporting.

§ 27.34. Reporting cases of lead poisoning.

The Department proposes to delete this section. The Department proposes to add reporting requirements for lead test results to the new charts in proposed §§ 27.21a and 27.22, and to update the reporting requirements as explained in those sections. The proposed addition of lead test results to the new charts for health care practitioners and facilities, and laboratories, will eliminate the need to have a separate section addressing the reporting requirements for lead poisoning and test results, and will make it easier for the regulated community to determine what diseases need to be reported, when and how.

§ 27.36. Reporting immunization delivery.

This proposed section is new.

Subsection (a)

The Department proposes, pursuant to its authority under section 16(a) of the act (35 P.S. § 521.16(a)), to require a health care practitioner, health care facility or individual authorized by law to administer immunizations to report the administration of the vaccine to the Department's designated immunization information system, unless the patient has declined the reporting of the immunization in writing. The Department proposes to require reporting in all counties of this Commonwealth, except Philadelphia County. The Department proposes to exclude vaccines given in Philadelphia County to prevent duplicate reporting because the Philadelphia Immunization Program of the City of Philadelphia's Department of Public Health manages a similar database that tracks every dose of vaccine given in the City of Philadelphia. *See* Department of Public Health, City of Philadelphia, Immunization Program. (2025). PhilaVax. Retrieved from https://vaccines.phila.gov/index.php/programs/#philavax. The Department proposes to include "unless the patient has declined" to permit a patient to opt out of having the patient's immunization information reported.

The Department currently has an immunization information system, but participation by a health care practitioner, health care facility or individual authorized by law to administer immunizations is voluntary. The proposed amendment will now require participation, unless a patient declines, which will greatly increase participation in the immunization information system and make it a more effective public health tool. The Department received positive feedback from stakeholders on now requiring health care practitioners, health care facilities or individuals authorized by law to administer immunizations to participate in the immunization information system.

The immunization information system helps providers and families by consolidating immunization information into one reliable source. CDC. (2024). Immunization Information

Systems Resources. Retrieved from https://www.cdc.gov/iis/about/index.html. The immunization information system allows providers to determine what immunizations a patient has received, regardless of where the patient received their previous immunizations, which will guide patient care and help ensure that the patient receives proper immunizations.

Additionally, patients can access their immunization information to help guide decisions regarding their immunizations. They may request a record of their immunizations, which may be required for education, employment, or other reasons. Further, the immunization information system helps the Department in supporting recommended immunizations. The immunization information system provides aggregate data on vaccinations for use in surveillance and program operations, such as improving vaccination rates and reducing vaccine-preventable diseases.

Some stakeholders suggested that the Department require participation without an opt out option by patients as they expressed that this defeats the purpose of the requirement. After consideration, the Department chose to keep the opt out option for patients as this language is based on Philadelphia County's current requirements. By mirroring the language with Philadelphia, this will make the entire Commonwealth consistent in its language and requirements. Philadelphia has also had this requirement for over 10 years, and it has proved to be a successful model. This requirement is consistent with other states, such as New Jersey, Delaware, Maryland and West Virginia. *See* N.J.A.C. 8:57-3.1 to app J; 16 Del. Admin. Code 4202-7.1.14; COMAR 10.06.03.01-09; and W. Va. Code R. § 64-7-6.

Subsection (b)

The Department proposes to require the vaccine administration report to be made within 30 days of administration of the vaccine, unless the Department requires it earlier during a public health emergency, or a different timeframe is required by law. This is consistent with

Philadelphia reporting requirements, and thus, will ensure that everyone who administers vaccines within the Commonwealth are adhering to the same reporting standards. The Department proposes to add language indicating that it may require submission earlier during a public health emergency and language indicating that a different timeframe may be required by law, as the timeframe for reporting may need to be expedited for various reasons, including allotment, distribution and tracking of immunizations.

Some stakeholders suggested that the 30-day timeframe for reporting be reduced as this may be too large of a time window. However, after consideration, the Department chose to keep the vaccine administration report within 30 days of administration as this proposed language is based on Philadelphia County's requirement that is currently in place. Mirroring requirements with Philadelphia will ensure that the entire Commonwealth is consistent. Additionally, Philadelphia has had this requirement for more than 10 years, and it has proven to be a successful model.

Subsection (c)

The Department proposes that the report submitted to the Department's immunization information system include the patient's name (first, middle and last), date of birth, gender, address, race and ethnicity. Requiring the patient's name, date of birth and address will help in identifying the individual that received the immunization. Knowing a patient's age as determined from the patient's date of birth, as well as the patient's gender, address, race and ethnicity will assist the Department in determining health disparities that may exist due to a wide variety of social factors. By identifying health disparities, the Department can respond and implement resources to address such disparities.

Subsection (d)

The Department proposes that the report contain certain vaccine information, including the type of vaccine, manufacturer, lot number, expiration date, vaccine administration code (CVX), date of vaccine administration and route of vaccine administration. This information will allow the Department to track vaccines and help ensure proper administration. In addition, if there are issues with product recalls, the information reported will help identify the people affected.

§ 27.37. Reporting birth defects and congenital anomalies.

This proposed section is new.

Subsection (a)

The Department proposes to create a birth defects registry and to require health care practitioners and health care facilities to report cases of certain birth defects and congenital anomalies through this registry within 180 work days of diagnosis. The reporting of birth defects will allow the Department to begin tracking birth defects within this Commonwealth and analyzing the data submitted through the registry to identify potential causes of birth defects and thus, work towards preventing them. The CDC helps support birth defect tracking systems in ten states in the United States. CDC. (2023). Birth Defects Research and Tracking. Retrieved from https://www.cdc.gov/birth-defects/tracking/.

The Department proposes, pursuant to its authority under section 16(a) of the act (35 P.S. § 521.16(a)), requiring reports of the following birth defects and congenital abnormalities: congenital malformations of the nervous system; congenital malformations of eye, ear, face and neck; congenital malformations of the circulatory system; congenital malformations of the respiratory system; cleft lip and cleft palate; other congenital malformations of the digestive system; congenital malformations of genital organs; congenital malformations of the urinary

system; congenital malformations and deformations of the musculoskeletal system; other congenital malformations; chromosomal abnormalities, not elsewhere classified; and abnormal findings on neonatal screening. The Department proposes to require reporting of these specific birth defects and congenital anomalies to align with ICD-10-CM, an international standard diagnostic classification system. CDC. (2022). ICD-10-CM Tabular List of Diseases and Injuries: Chapter 17, Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99). Listing diagnoses from the ICD-10 provides clarity as to which diagnoses are to be reported to the birth defect registry. Retrieved from https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf. The Department proposes to add the specific defects and anomalies listed in the ICD-10-CM rather than the ICD codes as these may change over time. The Department proposes to require reporting within 180 work days, which is much longer than other reporting requirements in this chapter, as the Department will not be actively responding to each report and will instead be maintaining the birth defect registry for tracking and use in preventing birth defects.

The Department also proposes a delayed effective date for the reporting requirements because the Department does not currently have a birth defects registry and will need to seek funding from the CDC to develop one. The Department has been unsuccessful in obtaining CDC funding in the past because this Commonwealth lacked statutory or regulatory language requiring birth defect reporting. Putting the requirement in regulation but delaying the effective date to accommodate the development and implementation of the registry will allow the Department time to obtain funding from either the CDC or the General Assembly, if funding from the CDC is unavailable, as well as time to create the birth defects registry. The Department

proposes to make the requirement effective 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry.

Subsection (b)

The Department proposes to include in subsection (b) which patients for whom a birth defect or congenital anomaly shall be reported and proposes language in paragraphs (1) and (2) to capture the various times during which a birth defect or congenital anomaly may be diagnosed. While prenatal screening tests can predict whether an infant is more or less likely to have a birth defect, an actual diagnosis is required. CDC. (2023). About Birth Defects. Retrieved from https://www.cdc.gov/birth-defects/about/. This diagnosis may occur immediately at birth, or in some cases, such as heart defects, may not occur until later in life. *Id*. In paragraph (1), the Department proposes to require reporting for infants who are born alive and are diagnosed before their first birthday. This would include infants who are born alive but die before their first birthday and are diagnosed with a birth defect or anomaly at the time of death. In paragraph (2), the Department proposes to require reporting for fetuses that are not born alive but have completed 19 weeks of gestation. In the absence of a gestational age estimate, a congenital anomaly in a fetus that is not born alive shall be reported if the fetus had a weight of at least 500 grams. The Department proposes such reporting to account for congenital anomalies which developed during pregnancy and may have attributed to the infant's death.

Subsection (c)

The Department proposes to add language indicating that the reporting requirements in this section apply to each infant or fetus born, expelled or extracted and to clarify that reporting of birth defects and congenital anomalies is required of all infants or fetuses, regardless of whether the infant or fetus is born alive. Requiring the reporting of birth defects for all infants,

regardless of birthing circumstances and regardless of whether they are born alive or not, aligns with the CDC and is necessary to understand and prevent birth defects. *See* CDC. (2024). Birth Defects Tracking. Retrieved from https://www.cdc.gov/birth-defects/tracking/index.html.

Reporting by Local Health Departments

The Department proposes to replace "morbidity reporting offices" with "health departments" in the content header for consistency in terminology.

§ 27.41a. Reporting by local morbidity reporting offices of case reports received.

The Department proposes to delete this section. As explained previously, the term "local morbidity reporting offices" or "LMRO" is an outdated term that was used to describe a district office of the Department or a local health department. The Department proposes to replace the terms "local morbidity reporting offices" and "LMRO" with "local health department" where these terms appear throughout the regulations. In practice, cases are reported to either the Department or local health department.

§ 27.42a. Reporting by local health departments of completed case investigations.

The Department proposes to replace the term "morbidity reporting offices" with "health departments" in the title of this section for consistency in terminology. Existing § 27.42a requires an LMRO that was not one of the Department's district offices to submit on a weekly basis, a case investigation report of the information from each case investigation to various divisions within the Department. This requirement is obsolete, not only because the term LMRO is outdated, but also because reporting is now done, for the most part, via the Department's electronic disease surveillance system. The Department proposes, in subsection (a), to continue requiring reports of the information from each case investigation that results in a confirmation of a reportable disease. The Department proposes to require submission within 7 days of the

completed investigation report, rather than on a weekly basis. This will give the local health department more time to complete its report. The Department proposes to require submission through the Department's electronic disease surveillance system for local health departments who have access to this system, or through other means for local health departments who do not have access to the Department's electronic disease surveillance system. One local health department has chosen not to utilize the Department's electronic disease surveillance system and has worked with the Department's Bureau of Epidemiology to provide the case investigation reports through other means. This proposed amendment reflects current practice between the Department and local health departments.

The Department proposes, in subsection (b), to require the case report to contain the information from each case investigation that has resulted in confirmation of a disease, infection or condition that is required to be reported under this chapter to ensure that local health departments are providing the Department with the same information as others who report to the Department's electronic disease surveillance system.

§ 27.43a. Reporting by local health departments of outbreaks and selected diseases.

The Department proposes to replace the words "morbidity reporting offices" with "health departments" in the title of this section for consistency in terminology. The Department also proposes to delete the words "and selected diseases" from the title of this section to align with the proposed deletion of the list of specific diseases currently outlined in this section. The Department proposes to delete the existing language in this section, which requires reporting by an "LMRO that is not one of the Department's district offices" by telephone, on the same day, to certain divisions within the Department, of an outbreak of AIDS, chancroid, chlamydia trachomatis infections, gonococcal infections, granuloma inguinale, lymphogranuloma

venereum, syphilis, tuberculosis, chickenpox, diphtheria, measles, mumps, pertussis, polio, rubella, tetanus, and other reportable diseases and conditions. Reporting of these specific diseases, infections and conditions occurs by providers reporting through the Department's electronic disease surveillance system in accordance with proposed § 27.21a(b), and thus, additional reporting by local health departments to the Department is not necessary and would be duplicative.

The Department proposes to add language requiring a local health department, instead, to report an outbreak, public health emergency or unusual occurrence of a disease, infection or condition to the Department in the time and manner specified in § 27.3 (relating to reporting outbreaks, public health emergencies and unusual diseases, infections and conditions). The Department proposes this language to ensure that reporting of outbreaks, public health emergencies and unusual occurrences of diseases, infections or conditions are being reported in the same timeframe and manner, regardless of who is doing the reporting.

Subchapter C. Disease Control Measures

The Department proposes to rename this subchapter from "quarantine and isolation" to "disease control measures" to more accurately reflect the substance of this subchapter which, as amended, would apply to a variety of disease control measures, not just quarantine and isolation.

General Provisions

§ 27.60. Disease control measures.

Subsection (a)

The Department proposes to add a comma and delete the word "or" after the words "communicable disease" and to add the words "or condition" after the word "infection" for consistency in the use of the term "disease, infection or condition" throughout the proposed

regulations and to make it clear that this section applies to infections as well as diseases and conditions. The Department also proposes to add the words "prevention, containment or mitigation" between the word "surveillance" and the words "of disease."

While isolation and quarantine are generally used to prevent, contain or mitigate a disease for those that have or have been exposed to the disease, there may be situations where other measures are necessary. For example, if a specific location poses a threat of disease, such as through an accident, spill or an isolated outbreak of disease, measures to restrict access or unprotected access to the affected location may be more vital to preventing, containing or mitigating new spread of disease than through isolation or quarantine. Measures less restrictive than isolation and quarantine could also be effective, such as use of a disinfectant, cleaning or social distancing. The Department also proposes to add the words "or toxins" after the words "infectious agents." As noted in other sections of this preamble, toxins can pose a significant threat to public health. Therefore, the Department proposes to add the word "toxins" to make it clear that disease control measures may be implemented to prevent, contain or mitigate disease caused by toxins.

Additionally, in *Corman v. Acting Secretary of Pennsylvania Department of Health*, 266 A.3d 452 (Pa. 2021), the Pennsylvania Supreme Court directly addressed this subsection while deciding whether the Department had authority to issue a school-wide masking mandate during the COVID-19 pandemic. The Court in *Corman* noted that the broad powers given to the Department to enforce disease control measures were restricted by regulation, and pursuant to the current language of § 27.60(a) "surveillance" is the only reason by which the Department can enact a disease control measure like school-wide masking. *See* 35 P.S. § 521.5. Ultimately the Court held that the Department lacked the power to issue the masking mandate, but notably

pointed out that "[o]f course, the Department has the power to promulgate a different regulation, or to amend this one, to . . . strip the 'any other disease control measure' catch-all of its limiting language." *Id*. at 484. The foregoing decision influenced the Department's proposed amendments to this subsection, which propose to add "prevention, containment or mitigation" as justifications for the implementation of all disease control measures available to the Department under the Disease Prevention and Control Law.

Subsection (b)

The Department proposes to add a comma and delete the word "or" after the word "disease" and to add the words "or "condition" after the word "infection" throughout this subsection to make it clear that disease control measures may be implemented for "conditions" as well as "diseases" and "infections" and for consistency in the use of the term "diseases, infections or conditions" throughout the regulations. The Department also proposes to add the words "if relevant" after the words "the type of facility available" for clarification. As part of disease control measures, a person may need to be isolated at a facility. For example, if the person has a highly dangerous and infectious disease like Ebola, the person may need to be isolated at a specialized facility that can handle such cases. For other diseases and conditions, isolating at home may be sufficient.

Subsection (c)

The Department proposes to replace the words "an LMRO" with the words "a local health department" for consistency in terminology.

§ 27.60a. Investigation of cases, outbreaks, public health emergencies and unusual occurrences of diseases, infections and conditions.

The Department proposes to move requirements pertaining to investigations from existing § 27.152 (relating to investigation of cases and outbreaks) to this section, with some amendments described below, so that all disease control measures are in one place, which will make it easier for the regulated community to find them. The Department proposes to add "public health emergencies and unusual occurrences of disease, infections and conditions" in the title to align with proposed amendments, described below.

Subsection (a)

The Department proposes to move language from existing § 27.152(a), into this subsection, indicating that the Department or a local health authority may investigate any case or outbreak of disease, but with amendment. The Department proposes to add that the Department or a local health authority may investigate public health emergencies and unusual occurrences of disease, infections and conditions in addition to cases and outbreaks. While public health emergencies and unusual occurrences of disease are made up of individual cases, and possibly one or more outbreaks, this language clarifies that they may also be investigated by the Department and a local health authority. The Department proposes not to carry over the words "judged by the Department or local health authority to be a potential threat to the public health." Cases, outbreaks, public health emergencies and unusual occurrences of disease reported to the Department would all be a potential threat to the public health and require measures by the Department, which is why they are reported.

Subsection (b)

The Department proposes to add language in this subsection, indicating that the Department or a local health authority may enter an apartment, a building, a health care facility, a school, college or university, or other location as necessary to conduct its investigation under

this chapter. Existing § 27.152(b) refers to the Department or a local health authority seeking to enter a house, health care facility, building or other premises to carry out an investigation. Moving this language into its own subsection and including the additional examples of apartment, school, college or university will make the language clearer to the regulated community.

Subsection (c)

The Department proposes to move the requirements from existing § 27.152(b) and (c) that a person not interfere with or obstruct a representative of the Department or local health authority from entering a location and that a person not interfere with or obstruct a review of medical records, but with amendment. The Department proposes to rephrase the requirement to indicate that a person shall not obstruct or interfere with the Department or local health authority's investigation under this chapter, to make the requirement clearer and to more broadly cover all aspects of the Department's investigative authority under this chapter. The Department does not propose to carry over the language from existing subsection (c), indicating that the Department or a local health authority may conduct a confidential review of medical records, as this will be covered in proposed § 27.60(e) (relating to confidential review of patient medical records).

§ 27.60b. Contact tracing and partner services, generally.

This proposed section is new and applies to contact tracing and partner services, generally. The Department proposes additional specific requirements for contact tracing and partner services in schools in proposed § 27.60c (relating to contact tracing and partner services in schools).

Subsection (a)

The Department proposes to add language indicating that the Department or local health authority may during an investigation under proposed § 27.60a (relating to investigation) enter an apartment, building, health care facility, school, college or university, or other location as necessary to carry out contact tracing or partner services. Contact tracing and partner services are necessary to interrupt disease transmission, and therefore vital to the prevention and control of diseases, infections and conditions. *See* Hossain, A.D. et al. (2022). "Effectiveness of Contact Tracing in the Control of Infectious Diseases: A Systematic Review." *Lancet Public Health*, 7(3), 259-273. Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC8847088/. Hogben, M. et al. (2016). "Partner Services in STD Prevention Programs: A Review." *Sexually Transmitted Diseases*, 43(2S): S53-S62. Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC4717997/.

Subsection (b)

The Department proposes to require a person to not obstruct or interfere with, the Department or local health authority conducting contact tracing or partner services under this section. This is similar to language used in proposed § 27.60a for investigations. Contract tracing and partner services are time-sensitive and are important for interrupting disease transmission and thus are important measures for disease prevention and control and must be conducted without obstruction or interference.

§ 27.60c. Contact tracing and partner services in schools.

This proposed section is new and contains similar language as proposed § 27.60b (relating to contact tracing and partner services, generally) but applies specifically to schools.

Subsection (a)

The Department proposes to require a school to provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises or attending a school function. The Department proposes this requirement to clarify that schools are subject to contact tracing and partner services as there has been confusion in the past regarding whether the existing provisions of the regulations specifically apply to schools. The proposed addition of "reasonable and timely" is intended to give schools the ability to provide access at a time that works for the school and the student, while still within the time necessary for the Department to conduct its investigation based on the infectious period of the disease in question.

Subsection (b)

The Department proposes to require a person, including an employee or official of a school, to permit the Department or local health authority to meet and speak with a student or other person, in private, and to prohibit the person from interfering with the student or other person's ability to exercise their right to give consent under 35 P.S. § 10103. Pursuant to 35 P.S. § 10103, "any minor may give effective consent for medical and health services to determine the presence of or to treat . . . venereal disease and other diseases reportable under the act April 23, 1956 (P.L. 1510), known as the 'Disease Prevention and Control Law of 1955,' and the consent of no other person shall be necessary."

Subsection (c)

The Department proposes to require a person, including an employee or official of a school, to not obstruct or interfere with the Department or local health authority conducting contact tracing or partner services under this section. Contract tracing and partner services are

time-sensitive and are important for interrupting disease transmission and thus are important measures for disease prevention and control and must be conducted without obstruction or interference.

§ 27.60d. Partner services relating to HIV, AIDS and other sexually transmitted and related diseases.

This proposed language is new. The Department proposes to require a health care practitioner, or other person, including an employee or official of a health care facility or community-based organization providing sexually transmitted disease, HIV or related test results to a patient to inform the patient that the Department or local health authority may contact the patient for a voluntary confidential interview to discuss partner services. Partner services, as defined in proposed § 27.1, are a "broad array of services offered to persons with HIV, sexually transmitted infections or other potentially sexually transmitted diseases, and their partners. The term includes partner elicitation and notification, treatment or linkage to HIV medical care, prevention counseling, treatment of partners for HIV or sexually transmitted infections, pre-exposure prophylaxis (PrEP), hepatitis screening and vaccination, and linkage or referral to other services, such as reproductive health services, prenatal care, substance use treatment, social support, housing assistance, legal services and mental health services." A health care provider is likely to be trusted by a patient. Requiring a health care practitioner or other person, including an employee or official of a health care facility or community-based organization, to provide notice that the Department or public health authority may contact them, will eliminate any surprise the patient may feel from being contacted. The patient may also be more willing to discuss partner services, which will not only help the patient, but also help interrupt disease transmission.

§ 27.60e. Confidential review of medical records.

The Department proposes to move requirements pertaining to review of medical records from existing § 27.152(c) to this section, with some amendments described below, so that all disease control measures are in one place, which will make it easier for the regulated community to find them.

Subsection (a)

The Department proposes to add language indicating that the Department or local health authority shall have access to and may conduct a confidential review of patient medical records maintained by health care practitioners, hospitals and other health care facilities. Existing § 27.152(c) indicates that the Department or local health authority may conduct a confidential review of medical records. The proposed addition of language to require "access to" these records will add clarity to this requirement because the Department or local health authority cannot conduct a review of medical records if they are not provided with access to the records. The Department also proposes to add language permitting the Department or local health authority to request copies of medical records and requiring submission of these copies electronically in a secure manner that is acceptable to the Department or local health authority. Review of medical records is necessary for the Department and local health authority to prevent and control disease. Access to the medical records may also be time sensitive and use of electronic transmission will expedite review. The Department and local health authority will verify that the electronic transmission is conducted in a secure manner to ensure confidentiality of the medical records.

Subsection (b)

The Department proposes to require a person to not obstruct or interfere with the review of patient medical records by the Department or local health authority. This is already required in the last sentence of existing § 27.152(c).

§ 27.61. Isolation.

The Department proposes to rephrase the existing language, which pertains to the isolation of a person or animal suspected of harboring an infectious agent. The Department proposes to indicate that the Department or local health authority will, when deemed necessary, direct that a person or animal be isolated until no longer capable of causing illness in others when the person or animal is known or strongly suspected of having an illness due to a chemical, biologic or radiologic agent capable of causing illness in others. The Department proposes this language to limit and clarify the circumstances in which the Department or local health authority will direct that a person or animal be isolated. Isolation will only be directed when it is necessary for the prevention and control of disease.

The Department proposes in paragraph (1) to replace the words "an LMRO" with the words "a local health department." As explained previously, the term "LMRO" is outdated, and the Department proposes to replace this term throughout the regulations with the more appropriate term, "local health department." The Department does not propose any amendments to paragraph (2).

The Department proposes, in paragraph (3), to replace the words "shall ensure that" with the words "will provide" before the word "instructions" and to delete the words "are given" to clarify the Department and local health authority's role in ensuring that instructions are provided when isolation is deemed necessary. The Department proposes to replace the words "defining the area in which the case is to be isolated and identifying the" with the words "where the case is

located." The Department proposes to end the sentence there and to add the words "the instructions will indicate the location where the case is to be isolated and will relay the" before the words "measures to be taken." The Department proposes these amendments to clarify the Department and local health authority's role and what will be provided in the instructions when isolation is deemed necessary.

§ 27.65. Quarantine.

The Department proposes to replace the words "authority which is also an LMRO" and the words "officer of the LMRO" with the word "department" to align with the use of the term "local health department" as used throughout the proposed regulations. The Department proposes to add a sentence stating that the instructions provided by the Department or local health department will indicate when contacts may be released from quarantine and will relay the measures to be taken to prevent the spread of disease. Similar to the provision in proposed § 27.61 (relating to isolation), this proposed language is intended to clarify for the regulated community the Department and local health department's role and responsibilities when quarantine is necessary.

The Department proposes amendments throughout this section, for grammatical reasons, to clarify the use of the term "quarantine" as it is defined in proposed § 27.1. The Department, proposes in paragraph (2), to add the words "and will ensure that appropriate disease prevention and control measures are being followed." This proposed amendment clarifies the Department and local health authority's role and responsibility to ensure that the instructions provided during a quarantine are followed.

§ 27.66. Placarding.

The Department proposes to replace the words "an LMRO" with the words "a local health department" for consistency in terminology.

§ 27.67. Movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department.

Subsection (a)

The Department proposes to replace the words "an LMRO" with the words "a local health department" for consistency in terminology.

Subsection (b)

The Department proposes to replace the word "the" with the word "another" before the word "jurisdiction" and to delete the words "of the Department or another local health authority" after the word "jurisdiction." This proposed amendment is not intended to change the original intent of the language, but to instead make it clear that removing a person or animal under isolation or quarantine to another jurisdiction requires permission of the Department, if it is involved, and with the permission of the local health authorities concerned. The Department also proposes to replace the word "LMROs" with the words "local health departments" for consistency in terminology.

Subsection (c)

The Department proposes to add "and a local health department if it is involved" to indicate that a local health department must also give permission, if involved, for interstate transportation to or from this Commonwealth for a person or animal under isolation or quarantine. This proposed amendment will ensure that local health departments are informed and are involved in situations involving interstate transport of persons or animals under isolation or quarantine.

Subsection (d)

The Department proposes to replace the words "an LMRO" with the words "a local health departments" for consistency in terminology. The Department also proposes to replace the words "to take due care" with the words "for following isolation or quarantine instructions" to remove ambiguity and to make it clear that the sender, receiver and transporter of a person or animal under isolation or quarantine are to follow isolation or quarantine instructions to prevent the spread of disease.

Subsection (e)

The Department proposes to replace the word "resumed" with the word "completed." As clarified in proposed amendments to subsection (d), the sender, receiver and transporter of a person or animal under isolation or quarantine is to follow isolation or quarantine instructions during transportation. Isolation or quarantine is not halted during the transportation process and therefore would not "resume" upon arrival. Therefore, the Department proposes to replace the word "resumed" with the word "completed" to clarify that the period of isolation or quarantine is to be completed upon arrival, instead of "resumed."

§ 27.68. Release from isolation or quarantine.

The Department proposes to replace the words "may order" with the words "that ordered" and to replace the words "isolated or quarantined under the direction of the Department or to the appropriate health authority be released" with the words "into isolation or quarantine may release that person or animal." The Department also proposes to replace the words "Department or the local health" with the word "appropriate" before the word "authority." The Department proposes these amendments to make it clear that whoever ordered isolation or quarantine, *i.e.*, the Department or the local health authority, is responsible for releasing the

person or animal under isolation or quarantine. The Department also proposes to replace the words "an LMRO" with the words "a local health department." As explained previously, the term "LMRO" is outdated, and the Department proposes to replace this term throughout the regulations with the more appropriate term, "local health department."

§ 27.69. Laboratory analysis.

The Department proposes to replace the word "organisms" with the word "agents." An "agent" is any microorganism that causes a disease and is more accurate than the term "organism." The Department also proposes to replace the words "approved by the Department to conduct that type of examination" with the words "authorized to conduct this type of examination under applicable State and Federal law" to account for laboratories outside of this Commonwealth that may process specimens for a health care practitioner within applicable State and Federal law requirements.

Communicable Diseases in Food Handlers, Health Care Practitioners, Students in Schools, Colleges and Universities, Children in a Child Care Group Setting, and Persons Who have Direct Contact with Students in a School, College or University or Children in a Child Care Group Setting

The Department proposes to amend the content header by replacing the words "in children and staff attending schools and child care group settings" with "food handlers, health care practitioners, students in schools, colleges and universities, children in a child care group setting, and persons who have direct contact with students in a school, college or university or children in a child care group setting." The Department proposes this amendment to align with proposed amendments in §§ 27.71—27.77, described below.

§ 27.71. Exclusion of children, and staff having contact with children, for specified diseases and infectious conditions.

The Department proposes to delete this section and to consolidate several existing sections pertaining to exclusion and readmission requirements in new, proposed § 27.71a (relating to exclusion and readmission requirements for specified diseases, infections and conditions of food handlers, health care practitioners, schools, colleges and universities, child care group settings, and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting), as explained below.

§ 27.71a. Exclusion and readmission requirements for specified diseases, infections and conditions of food handlers, health care practitioners, schools, colleges and universities, child care group settings, and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting.

The Department proposes to consolidate several existing sections pertaining to exclusion and readmission of persons with certain infections, conditions or diseases, within this new section, as well as expand requirements in those sections to include additional persons, as described below. The Department proposes to amend the title of this section from "exclusion of children, and staff having contact with children, for specified diseases and infectious conditions" to "exclusion and readmission of persons with specific diseases and infectious conditions who work or volunteer as food handlers or health care practitioners, students in schools, colleges or universities, children in child care group settings, and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting" to reflect these proposed amendments.

Subsection (a)

The Department proposes to require persons in charge of a school, college, university or child care group setting to adhere to exclusion and readmission requirements for certain diseases, infections and conditions. These persons are to adhere to these requirements for persons, and direct contacts of persons, attending, working, or volunteering in classes, programs or extracurricular activities who are suspected or confirmed by a health care practitioner, acting within their scope of practice, to have one of these specified diseases, infections or conditions.

Persons in charge of a public, private, parochial, Sunday or other school or college are already required to adhere to certain exclusion and readmission requirements under existing § 27.71. As explained in proposed § 27.1a, the Department proposes to add a definition for the term "school." This definition would encompass public, private, parochial, Sunday and other schools, and thus, eliminate the need to call those type of schools out specifically in the regulation. The Department proposes to add "universities" to the requirements for exclusion and readmission. The term "university" is often used interchangeably with the term "college," and this addition would thus be a simple clarification that the requirements apply to both colleges and universities.

The existing exclusion and readmission requirements in § 27.71 apply to children, and staff having contact with children in a school or college setting, who have the following diseases, infections and conditions: diphtheria, measles, mumps, pertussis, rubella, chickenpox, respiratory streptococcal infections including scarlet fever, infectious conjunctivitis (pink eye), ringworm, impetigo contagiosa, pediculosis capitis, pediculosis corpora, scabies, trachoma, tuberculosis, and Neisseria meningitidis. Existing § 27.75 (relating to exclusion of children, and staff having contact with children, during a measles outbreak) excludes children, and staff including volunteers, wo have contact with children, during a measles outbreak under the

procedures set forth in existing § 27.160 (relating to special requirements for measles). Existing § 27.76 (relating to exclusion and readmission of children, and staff including volunteers, having contact with children, in child care group settings) contains requirements pertaining to the exclusion and readmission of children, and staff having contact with children, in a child care group setting, who have the following diseases, infections and conditions: meningococcal meningitis or meningococcemia, haemophilus influenza (H. flu) meningitis or other invasive H. flu disease, persistent diarrhea, fever, hepatitis A, viral hepatitis unspecified, or jaundice of unspecified etiology, shigellosis, typhoid fever or paratyphoid fever, and exposure to an individual with meningococcal disease. Existing § 27.154 (relating to restrictions on caregivers in a child care group setting) restricts persons with the following diseases, infections and conditions from working as a care giver in a child care group setting, if the care giver works in a capacity requiring direct contact with children: amebiasis, enterohemorrhagic E. coli, shigellosis, typhoid fever or paratyphoid fever, hepatitis A, viral hepatitis, or jaundice of unspecified etiology, and persistent diarrhea. In addition to the above, existing §§ 27.156 through 27.160 contain special requirements, which include household contacts of those with the following diseases, infections and conditions: amebiasis, enterohemorrhagic E. coli, shigellosis, typhoid and paratyphoid fever and measles.

Subsection (a)

The Department in subsection (a) proposes to combine the above requirements for schools, colleges and universities, child care group settings, and direct contacts, into one place for ease of readability. The Department also proposes to place the requirements for the listed diseases, infections and conditions into chart format, similar to proposed §§ 27.21a and 27.22, for readability. The Department proposes to add "attending, working or volunteering in classes,

programs or extracurricular activities," which is intended to clarify to whom the exclusion and readmission requirements apply. In some cases, for example, with amebiasis, this results in an expansion of the existing requirements to individuals that were previously not excluded, such as volunteers. The Department has determined that the requirements for exclusion and readmission must include all individuals attending, working or volunteering to prevent and control the spread of disease in child care and school, college and university settings. The Department further proposes to include "school," "college," "university," and "child care group" setting to further clarify to whom each exclusion and readmission requirement applies. Below, the Department explains where exclusion and readmission requirements mirror, or differ, from any of the already existing requirements in §§ 27.71, 27.75, 27.76, 27.154 and 27.156 through 27.160.

Amebiasis

As mentioned previously, restrictions pertaining to cases of amebiasis already apply to caregivers in a child care group setting under existing § 27.154(1). That section restricts caregivers in a child care group setting, with amebiasis, from attending or working in a capacity that requires direct contact with children "until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed." The Department proposes to include this language in paragraph (i), but to change the term "antibacterial" to "antiparasitic" as this is the appropriate descriptor for the type of treatment that is given for amebiasis. The Department also proposes to replace "after treatment was completed" with "after the last dose of treatment was taken" for clarification. The Department also proposes to replace the word "obtained" with "collected" for consistency and verbiage. The Department further proposes to replace the

requirement for the specimen to be verified by a physician with a requirement for the specimen to be verified by an appropriate clinical laboratory. The Department proposes throughout to require verification by a clinical laboratory instead of a physician, as a clinical laboratory is the most appropriate entity to verify test results. The Department further proposes that the specimen be collected by a test deemed acceptable to the Department, such as an ova and parasite exam. An ova and parasite exam looks for ova or eggs of parasites. *See* CDC. (April 9, 2024). Diagnosis of Parasitic Disease. Retrieved from https://www.cdc.gov/parasites/testing-diagnosis/index.html. Allowing other tests deemed acceptable to the Department permits for new or alternative tests to also be utilized for testing.

As previously mentioned, existing § 27.156 also contains restrictions for household contacts, of cases of amebiasis, who attend or work in a child care group setting in a capacity which requires contact with children. These individuals are required to "cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antiparasitic therapy, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Entamoeba histolytica." The Department, in paragraph (ii), similarly proposes to require exclusion until the contact has "two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department. If the contact received antiparasitic treatment, the specimens may not be collected until 48 hours after the last dose of treatment was taken." This proposed amendment aligns with the proposed amendments in paragraph (i) for persons with amebiasis.

The Department, in proposed paragraph (iii), proposes to require exclusion of a toilet-trained person from a school setting if their amebiasis-associated diarrhea is causing uncontrolled

bowel movements. The Department, in proposed paragraph (iv), proposes to require readmission of a toilet-trained person when they regain control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day. The Department proposes to require exclusion and readmission based on symptoms as opposed to eradication of amebiasis for consistency with other enteric diseases, such as salmonella and shigellosis.

Campylobacter

The proposed addition of exclusion and readmission requirements for campylobacter is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with campylobacter-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the program day or the child's stool contains blood or mucus. This proposed requirement aligns with recommendations from the American Academy of Pediatrics (AAP) for exclusion in educational settings. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 80. The Department proposes in paragraph (ii) to require exclusion of a toilet-trained person from school and child care group settings if the person's campylobacter-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department proposes in paragraph (iii) to require readmission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a toilet-trained person when the person regains control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement also aligns with recommendations from the AAP. *Id*. The Department

does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. The Department does not believe that this symptom warrants exclusion, but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-trained person with diarrhea containing blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

C. difficile

The proposed addition of exclusion and readmission requirements for *C. difficile* is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with *C. difficile*-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount in the program day, or the child's stool is black or contains blood or mucous. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *Id*. at p. 86. The Department proposes in paragraph (ii) to require exclusion of a toilet-trained person from school and child care group settings if the person's *C. difficile*-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department proposes in paragraph (iii) to require admission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a toilet-trained person when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. The Department does not believe that this symptom warrants exclusion but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

Conjunctivitis, infectious (pink eye)

Existing § 27.71 already requires exclusion of a child, or staff person, including a volunteer, who has contact with children for infectious conjunctivitis (pink eye) "until judged not infective; that is, without a discharge." The Department proposes to instead exclude persons with infectious conjunctivitis from school and child care group settings if the person has a fever or behavior change. This proposed amendment aligns with the AAP, who does not recommend exclusion for those who have pink eye without fever or behavior changes. AAP. *Id*. at p. 49.

COVID-19

The proposed addition of exclusion and readmission requirements for COVID-19 is new. The Department proposes exclusion of a person with COVID-19 from school, college, university and child care group settings if the person is experiencing a fever and behavior changes, or a fever in combination with any sign or symptom of respiratory illness. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *Id*. at p. 88. The Department proposes to require readmission to school, college, university or a child care group setting 24 hours after resolution of fever without the use of fever reducing medications. This proposed requirement also aligns with recommendations from the AAP. *Id*.

Cryptosporidiosis

The proposed addition of exclusion and readmission requirements for cryptosporidiosis is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with cryptosporidiosis-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the time in the program day, or the child's stool contains blood or mucous. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *Id*. at p. 91. The Department proposes in paragraph (ii) to exclude a toilet-trained person from school and child care group settings if the person's cryptosporidiosis-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department proposes in paragraph (iii) to require admission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a

toilet-trained person when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement also aligns with recommendations from the AAP. *Id*. The Department does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. The Department does not believe that this symptom warrants exclusion but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-trained person with diarrhea that is contains blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

Diphtheria

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of diphtheria in children or staff, including volunteers, who have contact with children. Under existing § 27.71(1), children or staff, including volunteers, are to be excluded for two weeks from onset or until appropriate negative culture tests. The Department proposes to add diphtheria to the new chart, but with amendments.

In proposed paragraph (i), the Department proposes language excluding a person with diphtheria from school and child care group settings until the earlier of the following: 14 days after the onset of symptoms or after a health care practitioner acting within the scope of their

practice has confirmed an appropriate negative culture test. This proposed amendment aligns with the already existing language in § 27.71(1), apart from requiring a health care practitioner, rather than a school nurse providing the verification that the criteria for readmission has been met. This proposed amendment more accurately reflects that, in practice, a health care practitioner would be the one ordering the culture tests for the patient.

The Department, in paragraph (ii), proposes to add criteria, which would permit the Department, while conducting disease control measures under Subchapter C, to exclude persons, who are susceptible for diphtheria, from a school or child care group settings until the person provides proof that the person is not susceptible, receives a vaccine for diphtheria, or when no cases of diphtheria have occurred in the specific school or child care group setting for 14 days. The Department proposes this expansion to include susceptible persons for consistency in requirements for severe, vaccine preventable diseases, such as measles. The Department proposes to define a person susceptible for diphtheria as including a person who presents with no history of four age-appropriate doses of diphtheria vaccine while 15 months of age or older, does not have a history of diphtheria disease as set forth in a written record from a health care practitioner acting within the scope of their practice, does not demonstrate serological evidence of diphtheria immunity (the presence of antibodies to diphtheria determined by an enzyme-linked immunosorbent assay test or other comparable test), and was born before December 31, 1956, the date the vaccine for diphtheria became available. The Department proposes this definition to clarify that exclusion would be appropriate under this paragraph only in circumstances when a person is able to transmit the disease to another, due to an incomplete or absent history of vaccination or lack of natural immunity, to prevent the possibility of an outbreak among those, such as children, who are most vulnerable to severe disease.

Giardiasis

The proposed addition of exclusion and readmission requirements for giardiasis is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with giardiasis-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the time in the program day, or the child's stool contains blood or mucous. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *Id*. at p. 110. The Department proposes in paragraph (ii) to exclude a toilet-trained person from school and child care group settings if the person's giardiasis-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department proposes in paragraph (iii) to require admission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a toilet-trained person when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. *Id*. The Department does not believe that this symptom warrants exclusion but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-

trained person with diarrhea that contains blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

Haemophilus influenzae (H. flu) or other invasive H. flu disease

As mentioned previously, existing § 27.76 already contains exclusion and readmission criteria for suspected and confirmed cases of haemophilus influenzae (H. flu) or other invasive H. flu disease in children or staff, including volunteers, who have contact with children in child care group settings. Under existing § 27.76(2), children or staff, including volunteers, are to be excluded until made noninfectious by a course of rifampin or other drug which is effective against the nasopharyngeal carriage stage of this disease, or otherwise shown to be noninfective. The Department proposes to add haemophilus influenzae (H. flu) or other invasive H. flu disease to the new chart, but to require exclusion until 24 hours after initiation of medication that is effective against the nasopharyngeal carriage stage of the disease, as the nasopharyngeal carriage state is when the disease is infectious. Requiring treatment that is effective against the nasopharyngeal carriage state will permit a student to return without infecting other students. The Department also proposes to expand the exclusion and readmission criteria to include persons in school settings.

Hepatitis A, viral hepatitis unspecified or jaundice of unspecified etiology

As mentioned previously, existing § 27.76 already contains exclusion and readmission criteria for suspected and confirmed cases of hepatitis A, viral hepatitis unspecified or jaundice of unspecified etiology in children or staff, including volunteers, who have contact with children in child care group settings. Under existing § 27.76(2), children or staff, including volunteers,

are to be excluded until one week following the onset of jaundice, or two weeks following symptom onset or IgM antibody positivity if jaundice is not present. Existing § 27.154(5) contains the same requirements for persons who work as care givers, with direct contact with children, in child care group settings. The Department proposes to add hepatitis A, viral hepatitis unspecified or jaundice of unspecified etiology to the new chart, with amendments. The Department proposes to require verification from a health care practitioner acting within the scope of their practice in cases where jaundice is not present, and readmission is sought based on IgM antibody positivity. A test showing the presence of IgM antibodies alone cannot be used to rule out a current infection with hepatitis A. Therefore, a health care practitioner is needed to make a determination as to an individual's contagiousness. *See* AAP. (2021). *Red Book: 2021 Report of the Committee on Infectious Disease, 32nd ed.*, at p. 374. The Department also proposes to expand the exclusion and readmission criteria to include persons in school settings to align with recommendations of the AAP. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 115.

Herpes Simplex

The proposed addition of exclusion and readmission requirements for herpes simplex is new. The Department proposes in paragraph (i) to add language indicating that exclusion of a person with herpes simplex is not necessary unless the person has an ulcer or vesicle inside the mouth and cannot control drooling. The Department proposes to require readmission when the person's drooling can be controlled, or there are no ulcers or vesicles present in the person's mouth. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *Id*. at pp. 119-120.

The Department proposes in paragraph (ii) to exclude athletes participating in sports from practice or any sporting event until all blisters are fully scabbed over, and there are no new blisters and no swollen lymph nodes near the skin lesions. The Department proposes these stricter requirements for athletes because athletes, particularly those who engage in sports that have intense, constant, and close skin contact, such as wrestling and rugby, are at high risk of exposure and contracting herpes simplex. Adams, B. (2004). "New Strategies for the Diagnosis, Treatment, and Prevention of Herpes Simplex in Contact Sports." Current Sports Medicine Reports, 3(5), pp. 277-283. Because of the highly contagious and infectious nature of herpes simplex, it is imperative that athletes show no signs of infection before returning to practice or participating in sporting events.

Impetigo

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of impetigo contagiosa in children or staff, including volunteers, who have contact with children. Under existing § 27.71(10), children or staff, including volunteers, are to be excluded for twenty-four hours after the institution of appropriate treatment. The Department proposes to add impetigo, to the new chart, but to rename it to "impetigo" for consistency with references to "impetigo" elsewhere in the regulations. The Department also proposes to amend the exclusion and readmission requirements to specify that exclusion of a person with impetigo is not necessary before the end of the program day if the lesions are washed and covered upon discovery. The Department proposes that the person confer with a health care practitioner acting within the scope of their practice, at the end of the program day, to confirm or deny a diagnosis of impetigo before readmission. The Department proposes to require readmission, if the diagnosis is confirmed, of the person the day after

treatment has begun, so long as all lesions are covered until dry. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 49, 123-124.

Influenza

The proposed addition of exclusion and readmission requirements for influenza is new. The Department proposes to require exclusion of a person with influenza from school, college, university or child care group settings if the person is experiencing a fever and behavioral change, or a fever in combination with any sign or symptom of respiratory illness. The Department proposes to require readmission 24 hours after the resolution of fever without the use of fever reducing medication. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *Id*. at pp. 125-126.

Lice (head or body)

The proposed addition of exclusion and readmission requirements for lice (head or body) is new. The Department proposes to add language indicating that exclusion of a person with head or body lice is not necessary before the end of the program day. The Department proposes to require readmission once treatment has begun, and no lice are present. The Department proposes to require that activities involving shared clothing or soft toys and head-to-head exposure be avoided until there are no lice or nits present. This proposed requirement generally aligns with recommendations from the AAP for exclusion and readmission in educational settings. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 127-129; and AAP. (2021). *Red Book: 2021 Report of the Committee on Infectious Disease, 32nd ed.*, at p. 571. The Department also proposes to require

the avoidance of activities involving shared clothing or soft toys, and head-to-head exposure, because lice may cling to these items and survive for up to 48 hours, during which time they may find a new host. Mayo Clinic. (2022). Lice – Overview. Retrieved from https://www.mayoclinic.org/diseases-conditions/lice/symptoms-causes/syc-20374399.

Measles

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of measles in children or staff, including volunteers, who have contact with children. Under existing § 27.71(3), children or staff, including volunteers, are to be excluded for four days from the onset of rash. Special requirements for measles exist currently in § 27.160 (relating to special requirements for measles) and require isolation for infected persons for four days after the appearance of the measles rash, as well. Section 27.160 also permits the Department to order exclusion of a person susceptible of infection from measles from school and child care settings unless the person presents evidence of having received a measles vaccination within 30 days prior to an outbreak, the person receives a measles vaccination, or no case of measles has occurred within the school or child care setting for a 14-day period. Section 27.160 defines a susceptible person as a person who presents no history of two doses of measles vaccination, separated by at least one month while 12 months of age or older, a person who does not demonstrate serological evidence of measles (the presence of antibodies to measles as demonstrated by a hemagglutination inhibition test or a comparable test), or a person who was born before December 31, 1956. The Department proposes to add measles to the new chart, but with amendments described below.

The Department proposes, in paragraph (i), to require a person with measles to be excluded from school, college, university or child care group settings until four days after the

day of rash onset, which mirrors existing §§ 27.71(3) and 27.160, but to add a requirement that the person's fever be resolved at least 24 hours for readmission as fever is one of the first symptoms to appear before the onset of rash. *See* CDC. (2024). Measles Symptoms and Complications. Retrieved from https://www.cdc.gov/measles/signs-symptoms/index.html.

The Department, in paragraph (ii), proposes to add criteria, which would permit the Department, while conducting disease control measures under Subchapter C, to exclude persons, who are susceptible for measles, from a school, college, university or child care group settings until the person provides proof that the person is not susceptible, receives a vaccine for measles, or when no cases of measles have occurred in the specific school, college, university or child care group setting for 21 days. The Department proposes to define a person susceptible for measles as including a person who presents with no history of two age-appropriate doses of measles vaccine while 12 months of age or older with the doses given at least one month apart, does not have a history of measles disease as set forth in a written record from a health care practitioner acting within the scope of their practice, does not demonstrate serological evidence of measles immunity (the presence of antibodies to measles determined by a hemagglutination inhibition test or a comparable test), or was born before December 31, 1956.

This proposed amendment mirrors existing § 27.160, which the Department proposes to delete so that requirements for exclusion and readmission are in the same section, with one exception. The Department proposes to expand the absence of measles cases in the school, college, university or child care group setting from 14-days to 21-days. This proposed amendment aligns with recommendations from the AAP and the CDC, who both recommend exclusion of susceptible persons for 21 days after the onset of rash in the last case of measles. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference*

Guide, 6th ed., at pp. 135-136; CDC. (2019). Manual for the Surveillance of Vaccine-Preventable Diseases, Chapter 7: Measles. Retrieved from https://www.cdc.gov/surv-manual/php/table-of-contents/chapter-7-measles.html.

Meningococcal meningitis, meningococcemia or infectious meningitis

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of *Neisseria meningitidis* in children or staff, including volunteers, who have contact with children. Under existing § 27.71(16), children or staff, including volunteers, are to be excluded until judged noninfective after a course of rifampin or other drug which is effective against the nasopharyngeal carriage state of this disease, or until otherwise shown to be noninfective. The Department proposes to add *Neisseria meningitidis*, to the new chart, but to rename it to "meningococcal meningitis; meningococcemia or infectious meningitis" for consistency with references to "meningococcal meningitis; meningococcemia or infectious meningitis" elsewhere in the regulations.

The Department also proposes to amend the exclusion and readmission requirements to specify that a person with meningococcal meningitis, meningococcemia, or infectious meningitis shall be excluded from school and child care group settings until 24 hours after initiation of medication that is effective against the nasopharyngeal carriage stage of this disease, or until the person is judged noninfectious by a health care practitioner acting within the scope of their practice. The proposed requirement for exclusion until 24 hours after initiation of medication aligns with recommendations from the AAP. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 137-138. The Department proposes to retain the option for the person to be "judged noninfective" by a health care practitioner, which exists in the current regulation.

Mononucleosis

The proposed addition of exclusion and readmission requirements for mononucleosis is new. The Department proposes to indicate that exclusion of a person with mononucleosis is not necessary, but to require exclusion from contact sports if a person with mononucleosis has an enlarged spleen until that symptom resolves. This proposed amendment aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings. *Id*. at p. 142.

Methicillin-resistant Staphylococcus aureus (MRSA)

The proposed addition of exclusion and readmission requirements for methicillin-resistant Staphylococcus aureus (MRSA) is new. The Department proposes to add language indicating that exclusion of a person with MRSA is not necessary, unless directed by a health care practitioner acting within the scope of their practice, so long as the infected skin is covered with a clean, dry bandage to prevent others and objects from coming into contact with the infected skin. The Department proposes to require that the bandage be inspected frequently and changed before drainage is visible through the bandage. This proposed amendment aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings, except for the additional requirements pertaining to bandaging. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 177-178. The Department proposes these additional requirements to ensure that drainage from the person's infected skin does not transmit the bacteria that causes MRSA to others. *See*, *e.g.*, CDC. (2024). Athletes: MRSA Prevention and Control. Retrieved from https://www.cdc.gov/mrsa/prevention/athletes.html (indicating that pus from infected wounds can contain MRSA).

Mumps

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of mumps in children or staff, including volunteers, who have contact with children. Under existing § 27.71(3), children or staff, including volunteers, are to be excluded for nine days from onset or until subsidence of swelling. The Department proposes to add mumps to the new chart, but with amendments.

In proposed paragraph (i), the Department proposes language excluding a person with mumps from school and child care group settings until the earlier of the following: complete subsidence of swelling, or 5 days after the onset of swelling. This proposed amendment aligns with recommendations from the AAP for exclusion and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 150.

The Department, in paragraph (ii), proposes to add criteria, which would permit the Department, while conducting disease control measures under Subchapter C, to exclude persons, who are susceptible for mumps, from a school or child care group settings until the person provides proof that the person is not susceptible, receives a vaccine for mumps, or when no cases of mumps have occurred in the specific school or child care group setting for 26 days. The Department proposes this expansion to include susceptible persons for consistency in requirements for severe, vaccine preventable diseases, such as measles. The Department proposes to define a person susceptible for mumps as including a person who presents with no history of two age-appropriate doses of the mumps vaccine while 12 months of age or older, does not have a history of mumps disease as set forth in a written record from a health care practitioner acting within the scope of their practice, does not demonstrate serological evidence

of mumps immunity (the presence of antibodies to mumps determined by an enzyme-linked immunosorbent assay test or other comparable test), and was born before December 31, 1956, the date the mumps vaccine became available. The Department proposes this definition to clarify that exclusion would be appropriate under this paragraph only in circumstances when a person is able to transmit the disease to another, due to an incomplete or absent history of vaccination or lack of natural immunity, to prevent the possibility of an outbreak among those, such as children, who are most vulnerable to severe disease.

Norovirus

The proposed addition of exclusion and readmission requirements for norovirus is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with norovirus-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the time in the program day, or the child's stool contains blood or mucous. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 152. The Department proposes in paragraph (ii) to exclude a toilet-trained person from school and child care group settings if the person's norovirus-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id.*

The Department proposes in paragraph (iii) to require admission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a toilet-trained person when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day. This

proposed requirement also aligns with recommendations from the AAP. *Id*. The Department does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. The Department does not believe that this symptom warrants exclusion, but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as black, bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

Pertussis (whooping cough)

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of pertussis (whooping cough) in children or staff, including volunteers, who have contact with children. Under existing § 27.71(4), children or staff, including volunteers, are to be excluded for three weeks from onset or 5 days from institution of appropriate antimicrobial therapy. The Department proposes to add pertussis to the new chart, but with amendments.

The Department proposes in paragraph (i) to exclude a person with pertussis until the earlier of the following: 5 days from the initiation of appropriate antimicrobial therapy or 21 days after the day of cough onset if the person is untreated. The Department proposes in paragraph (ii) to exclude a person who is coughing, who has had close contact with a case of

pertussis, until the earlier of the following: a health care practitioner acting within the scope of their practice has determined that the person has a diagnosis other than pertussis, the person has completed 5 days of appropriate antimicrobial therapy, or 21 days has passed since cough onset if the person is untreated. The Department proposes these changes from the requirements in existing § 27.71(4) to align with recommendations from the AAP for exclusion and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 195-196.

The Department, in paragraph (iii), proposes to add criteria, which would permit the Department, while conducting disease control measures under Subchapter C, to exclude persons, who are susceptible for pertussis, from a school or child care group setting until the person provides proof that the person is not susceptible, receives a vaccine for pertussis, or when no cases of pertussis have occurred in the specific school or child care group setting for 21 days. The Department proposes this expansion to include susceptible persons for consistency in requirements for severe, vaccine preventable diseases, such as measles. The Department proposes to define a person susceptible for pertussis as a person who presents with no history of four age-appropriate doses of pertussis vaccination while 15 months of age or older, does not have a diagnosis of pertussis as set forth in a written record from a health care practitioner acting within the scope of their practice, does not demonstrate serological evidence of pertussis immunity (the presence of antibodies to pertussis determined by an enzyme-linked immunosorbent assay test or other comparable test), and was born before December 31, 1956, the date the pertussis vaccination became available. The Department proposes this definition to clarify that exclusion would be appropriate under this paragraph only in circumstances when a person is able to transmit the disease to another, due to an incomplete or absent history of

vaccination or lack of natural immunity, to prevent the possibility of an outbreak among those, such as children, who are most vulnerable to severe disease.

Poliomyelitis

The proposed addition of exclusion and readmission requirements for poliomyelitis is new. Poliomyelitis (polio) is a debilitating infection with poliovirus that can cause meningitis and disabling or deadly paralysis. CDC. (2024). About Polio in the United States. Retrieved from https://www.cdc.gov/polio/about/index.html. There is no cure or specific treatment for polio. *Id*. The United States experienced its first case of paralytic poliomyelitis in over ten years in 2022, showing that the disease still poses a threat to those who are not vaccinated against the disease. *See* Children's Hospital of Philadelphia. (2023). 2022 New York Polio Case: Why and What Does it Mean? Retrieved from https://polionetwork.org/archive/ept6bxbkhzdimdqvbte0xc1um8gve3.

The Department, in paragraph (i), proposes to require exclusion of a person with poliomyelitis from school and child care group settings until the etiological organism has been eradicated, as proven by three negative stool specimens collected 24 hours apart, on three consecutive days, as verified by an appropriate clinical laboratory. The Department proposes this requirement to align with the CDC, who recommends the collection of two stool specimens at least 24 hours apart and within 14 days of onset of symptoms. *See* CDC. (2024). Pink Book, Chapter 18: Poliomyelitis. Retrieved from https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-18-poliomyelitis.html.

The Department, in paragraph (ii), proposes to require exclusion of a person with flu-like symptoms, or meningitis, that has had close contact with a case of poliomyelitis from school and child care group settings for a minimum of seven days after the person's last exposure. The

Department proposes to require readmission if the person has obtained two consecutive negative stool specimens three days after the person's last contact, with 24 to 48 hours between samples, as verified by an appropriate clinical laboratory. The Department this requirement to align with the World Health Organization (WHO), who recommends isolation for 7 days, even if a test is negative, and two negative stool samples taken 24 to 48 hours apart, starting three days after the contact's first exposure. *See* WHO. (2020). Public Health Management of Facility-Related Exposure to Live Polioviruses. Retrieved from https://iris.who.int/bitstream/handle/10665/379480/9789240007840-eng.pdf

Rotavirus

The proposed addition of exclusion and readmission requirements for rotavirus is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with rotavirus-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the time in the program day, or the child's stool contains blood or mucous. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission in educational settings. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 166. The Department proposes in paragraph (ii) to exclude a toilet-trained person from school and child care group settings if the person's rotavirus-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department proposes in paragraph (iii) to require admission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a toilet-trained person when the person regains control of bowel movements, and when stool

frequency is no more than two stools above normal for that person during the program day. This proposed requirement also aligns with recommendations from the AAP. *Id*. The Department does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. *Id*. The Department does not believe that this symptom warrants exclusion, but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-trained person with diarrhea that contains blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

Rubella

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of rubella in children or staff, including volunteers, who have contact with children. Under existing § 27.71(5), children or staff, including volunteers, are to be excluded for four days from the onset of rash. The Department proposes to add rubella to the new chart, but with amendments.

In proposed paragraph (i), the Department proposes language to require exclusion of a person with rubella from school and child care group settings for seven days after the onset of rash. This proposed expansion from 4 days to 7 days aligns with recommendations from the

AAP for exclusion and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 168.

The Department, in paragraph (ii), proposes to add criteria, which would permit the Department, while conducting disease control measures under Subchapter C, to exclude persons, who are susceptible for rubella, from a school or child care group settings until the person provides proof that the person is not susceptible, receives a vaccine for rubella, or when no cases of rubella have occurred in the specific school or child care group setting for 21 days. The Department proposes this expansion to include susceptible persons for consistency in requirements for severe, vaccine preventable diseases, such as measles. The Department proposes to define a person susceptible for rubella as a person who presents no history of one age-appropriate dose of rubella vaccination while 12 months of age or older, does not have a diagnosis of rubella disease as set forth in a written record from a health care practitioner acting within the scope of their practice, does not demonstrate serological evidence of rubella immunity (the presence of antibodies to rubella determined by the enzyme-linked immunosorbent assay test or a comparable test), and was born before December 31, 1956, the date the rubella vaccine became available. The Department proposes this exclusion to clarify that that exclusion would be appropriate under this paragraph only in circumstances when a person is able to transmit the disease to another, due to an incomplete or absent history of vaccination or lack of natural immunity, to prevent the possibility of an outbreak among those, such as children, who are most vulnerable to severe disease.

Salmonella

The proposed addition of exclusion and readmission requirements for salmonella is new. The Department proposes in paragraph (i) to require exclusion of a diapered child with

salmonella-associated diarrhea from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount in the program day, or the child's stool is black or contains blood or mucous. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 170. The Department proposes in paragraph (ii) to require exclusion of a toilet-trained person from school and child care group settings if the person's salmonella-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement also aligns with recommendations from the AAP. *Id*.

The Department proposes in paragraph (iii) to require admission of a diapered child when the child's stool is contained by a diaper, even if the stool remains loose, and readmission of a toilet-trained person when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement also aligns with recommendations from the AAP. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 170. The Department does not propose to adopt the AAP's recommendation for exclusion if the child has a dry mouth, no tears, or no urine output in eight hours, suggesting the child's symptoms may be causing dehydration. The Department does not believe that this symptom warrants exclusion but rather should be regarded as an indicator that the child may need to be seen by a health care practitioner.

The Department proposes in paragraph (iv) to require clearance from a health care practitioner acting within the scope of their practice for readmission of a diapered child or toilet-

trained person with diarrhea that is black or contains blood or mucous. This proposed requirement is not part of the AAP's recommendations. However, the Department considers this to be necessary as bloody or mucous-containing diarrhea is indicative of severe infection, for which readmission could endanger the person and all others within the setting.

Scabies

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of scabies in children or staff, including volunteers, who have contact with children. Under existing § 27.71(13), children or staff, including volunteers, are to be excluded after completion of appropriate treatment. The Department proposes to add scabies to the new chart, but with amendments.

The Department proposes to replace the existing requirement with language indicating that exclusion of a person with scabies is not necessary before the end of the program day. The Department proposes to require a person with a suspected infection of scabies to confer with a health care practitioner acting within the scope of their practice to confirm or deny a diagnosis of scabies before the person is readmitted. The Department proposes that if a diagnosis of scabies is confirmed, then the person shall be readmitted once the first course of treatment has been completed. This proposed language aligns generally with recommendations from the AAP, except that the Department proposes to permit persons to be readmitted after the first course of treatment has been completed instead of treatment being completed in its entirety. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 172. The Department proposes to permit readmission after completion of the first course of treatment because scabies has a propensity to require multiple treatments but is not infectious

after treatment has begun. *See* Cedars-Sinai. (2024). Scabies. Retrieved from https://www.cedars-sinai.org/health-library/diseases-and-conditions/s/scabies.html.

Shiga toxin-producing Escherichia coli (i.e., STEC)

Restrictions pertaining to cases of enterohemorrhagic E. coli already apply to caregivers in a child care group setting under existing § 27.154(2). That section restricts caregivers in a child care group setting, with enterohemorrhagic E. coli, from attending or working in a capacity that requires direct contact with children until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician; if antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. Existing § 27.157 extends this requirement to household contacts. The Department proposes to retain these exclusions in paragraphs (i) and (ii), but with amendments. The Department proposes to refer to "enterohemorrhagic E. coli" as "Shiga toxin-producing Escherichia coli (*i.e.*, STEC)" as this is the more commonly known term for enterohemorrhagic E. coli. The Department proposes to also add that the negative stool specimens must be collected by an appropriate clinical laboratory, instead of a physician. The Department proposes throughout to require verification by a clinical laboratory instead of a physician, as a clinical laboratory is the most appropriate entity to verify test results. The Department also proposes to require a test deemed acceptable to the Department, such as a culture or culture independent diagnostic test. The Department also proposes throughout to clarify that laboratory testing may be conducted using either a culture or culture-independent diagnostic test. Culture-independent diagnostic tests can detect the presence of a gene or antigen associated with a specific pathogen, can be conducted more rapidly and yield results far sooner than traditional culture-based methods, and are widely used by clinical laboratories. CDC.

(2024). Foodborne Illness and Culture-Independent Diagnostic Tests. Retrieved from https://www.cdc.gov/foodnet/reports/cidt.html. Allowing other tests deemed acceptable to the Department, in addition to culture or culture-independent diagnostic tests permits for new or alternative tests to also be utilized for testing.

The Department proposes, in paragraph (iii), to add that a toilet-trained person shall be excluded from school settings if the person's STEC-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings, for diarrhea generally. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at p. 50. The Department proposes, in paragraph (iv), to add that a toilet-trained person shall be readmitted when the person regains control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings. *Id.*

Shigellosis

As mentioned previously, existing § 27.76 already contains exclusion and readmission criteria for suspected and confirmed cases of shigellosis in children or staff, including volunteers, who have contact with children in child care group settings. Under existing § 27.76(6), children or staff, including volunteers, are to be excluded until the etiologic organism is eradicated. The Department, in paragraph (i), proposes to require exclusion of a person with shigellosis from child care group settings until the etiologic organism has been eradicated as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture

or a culture-independent diagnostic test. If antibacterial treatment has been given, the specimens may not be collected until 48 hours after the last dose of treatment. The Department proposes this amendment to align with other states that have the same requirements, such as New Jersey, Washington and Iowa. *See* New Jersey Department of Health. (2018). Shigellosis (*Shigella* spp). Retrieved from https://www.nj.gov/health/cd/documents/chapters/shigellosis_ch.pdf; Washington State Department of Health. (2022). Shigellosis. Retrieved from https://doh.wa.gov/sites/default/files/legacy/Documents/5100/420-079-Guideline-Shigellosis.pdf; and Iowa Health & Human Services. (2024). Controlling Spread of Shigellosis. Retrieved from https://hhs.iowa.gov/public-health/center-acute-disease-epidemiology/epi-manual/reportable-diseases/shigellosis-0. This proposed amendment also aligns with the AAP, who recommends exclusion until a state health department has deemed it safe for the individual to return. *See* AAP. (2021). *Red Book: 2021 Report of the Committee on Infectious Disease, 32nd ed.*, at pp. 131, 671.

Special requirements exist currently at § 27.158 (relating to special requirements for shigellosis) for household contacts of those who attend or work in a child care group setting in a capacity that requires contact with children, among others. Under § 27.158, a household contact of a person with shigellosis is required to cease work until the contact submits two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antimicrobial therapy, to an appropriate clinical laboratory for bacteriologic examination and the specimens are determined to be negative for shigella. The Department proposes to retain this requirement in paragraph (ii), with minor amendments for readability, for consistency with paragraph (i) and to clarify that the specimen may be tested using either a culture or culture-independent diagnostic test. The Department proposes throughout to clarify that laboratory

testing may be conducted using either a culture or culture-independent diagnostic test. Culture-independent diagnostic tests can detect the presence of a gene or antigen associated with a specific pathogen, can be conducted more rapidly and yield results far sooner than traditional culture-based methods, and are widely used by clinical laboratories. CDC. (2024). Foodborne Illness and Culture-Independent Diagnostic Tests. Retrieved from https://www.cdc.gov/foodnet/reports/cidt.html.

The Department proposes, in paragraph (iii), to add that a toilet-trained person shall be excluded from school settings if the person's Shigella-associated diarrhea is causing uncontrolled bowel movements. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings. *See* AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 173-174.

The Department proposes, in paragraph (iv), to add that a toilet-trained person shall be readmitted when the person regains control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in child care group settings. *Id*.

Shingles

The proposed addition of exclusion and readmission requirements for shingles is new. The Department proposes to add language indicating that exclusion of a person with shingles is not necessary, unless directed by a health care practitioner acting within the scope of their practice, so long as the rash is covered with clothing or a clean, dry bandage to prevent others and objects from coming into contact with the rash. The Department proposes to add that if the

rash cannot be covered, the person shall be readmitted once all blisters have dried and crusted. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 175-176.

Streptococcal respiratory infection (including strep throat and scarlet fever)

Existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of respiratory streptococcal infections including scarlet fever in children or staff, including volunteers, who have contact with children. Under existing § 27.71(7), children or staff, including volunteers, are to be excluded for at least 10 days from the onset if no physician is in attendance or 24 hours after institution of appropriate antimicrobial therapy. The Department proposes to add "strep throat" for clarity. Both strep throat and scarlet fever are caused by group A Streptococcus bacteria, with scarlet fever resulting from a strep infection of the throat or another area of the body. The AAP recommends exclusion, for both strep throat and scarlet fever, until the person has completed 12 hours of antibiotic treatment as prescribed by a health care practitioner acting within the scope of their practice. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 42, 179-180. The Department proposes to amend the exclusion requirement for streptococcal respiratory infection (including strep throat and scarlet fever) to align with the AAP. Research has shown that those infected with strep do not pose a risk to others once they have received their first 12 hours of antibiotic treatment. *Id*.

Tinea (ringworm)

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of tinea (ringworm) in children or staff, including

volunteers, who have contact with children. Under existing § 27.71(9), children or staff, including volunteers, shall be allowed to return immediately after the first treatment, if body lesions are covered; however, neither scalp nor body lesions that are dried need to be covered. The Department proposes to add tinea (ringworm) to the new chart, but with amendments. First, the Department proposes to replace the term "ringworm" with "tinea (ringworm)." Although these terms are interchangeable, tinea is the medically accepted name for the disease and encompasses other colloquial names for the same infection affecting different parts of the body, such as athlete's foot and jock itch.

The Department proposes to mirror the existing language in § 27.71(9), but to reword the language for clarity by indicating that exclusion of a person with ringworm is not necessary before the end of the program day if the person's lesions are covered, and to require readmission once treatment has begun so long as all lesions are covered until dry. The Department proposes to add language prohibiting athletes in sports with person-to-person contact and active ringworm infections of the body from participating in sports matches for 72 hours after starting treatment unless the infected area can be covered. The Department proposes this amendment to align with recommendations from the AAP for exclusion and readmission and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 161-162.

Tuberculosis

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of tuberculosis in children or staff, including volunteers, who have contact with children. Under existing § 27.71(15), children or staff, including volunteers, may be readmitted following a minimum of 2 weeks adequate

chemotherapy and three consecutive negative morning sputum smears, if obtainable, with submission of a note from the attending physician that the person's disease is in a noncommunicable stage. The Department proposes to retain this requirement, except for the requirement for "three consecutive negative morning sputum smears, if obtainable." The requirement for three consecutive negative morning sputum smears was based on older CDC guidance, which no longer reflects current practice. The Department also proposes to include a cross-reference to existing § 27.161 (relating to special requirements for tuberculosis), rather than including the requirements from that section in the chart, due to the unique challenges that tuberculosis treatment and related countermeasures present.

Typhoid fever or paratyphoid fever

As mentioned previously, existing § 27.76 already contains exclusion and readmission criteria for suspected and confirmed cases of typhoid fever or paratyphoid fever in children or staff, including volunteers, who have contact with children in a child care group setting. Under existing § 27.76(7), children or staff, including volunteers, are to be excluded until the etiologic organism is eradicated. The Department proposes to require exclusion until the etiological organism has been eradicated, as proven by three negative successive stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If antibacterial treatment or treatment with another chemotherapeutic drug effective against *Salmonella typhi* or *Salmonella paratyphi* was given, the specimens may not be collected until 48 hours after the last dose of treatment was taken. Specimens may not be collected earlier than 30 days after onset of symptoms. The Department proposes this amendment to align with the AAP. *See* AAP. (2021). *Red Book: 2021 Report of the Committee on Infectious Disease, 32nd ed.*, at pp. 660-61.

Existing § 27.159 extends exclusion to household contacts and chronic carriers who attend or work in a child care group setting in a capacity that involves contact with children. Existing § 27.159(a) and (b) excludes asymptomatic and symptomatic household contacts until the contact had submitted two stool specimens, taken at least 24 hours apart, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Salmonella typhi or Salmonella paratyphi. The Department proposes to retain this exclusion in subparagraph (ii) without distinguishing between asymptomatic and symptomatic contacts as the requirements are the same for both, except that symptomatic household contacts must have specimens collected no earlier than 30 days after onset of symptoms instead of 1 month, as the number of days within a month may vary. Existing § 27.159(c) excludes chronic carriers until three consecutive negative fecal cultures are obtained from specimens taken at least 1 month apart and at least 48 hours after antibiotic therapy has stopped. The Department proposes to retain this exclusion in subparagraph (ii) but with amendment from 1 month to 30 days to be more specific as the number of days within a month may vary.

Varicella (chickenpox)

As mentioned previously, existing § 27.71 already contains exclusion and readmission criteria for suspected and confirmed cases of chickenpox in children or staff, including volunteers, who have contact with children. Under existing § 27.71(6), children or staff, including volunteers, are to be excluded for 5 days from the appearance of the first crop of vesicles, or when all the lesions have dried and crusted, whichever is sooner. The Department proposes to add chickenpox to the new chart, but with amendments.

First, the Department proposes to add "varicella" to "chickenpox" for consistency in how chickenpox is referenced throughout the regulations. The Department proposes in paragraph (i) to exclude a person with varicella (chickenpox) from school and child care group settings until all lesions have dried and crusted, and no new bumps or lesions have appeared for at least 24 hours. This proposed requirement aligns with recommendations from the AAP for exclusion and readmission and readmission in educational settings. AAP. (2023). *Managing Infectious Diseases in Child Care and Schools, A Quick Reference Guide, 6th ed.*, at pp. 81-83.

The Department, in paragraph (ii), proposes to add criteria, which would permit the Department, while conducting disease control measures under Subchapter C, to exclude persons, who are susceptible for varicella (chickenpox), from a school or child care group setting until the person provides proof that the person is not susceptible, receives a vaccine for varicella, or when no cases of varicella have occurred in the specific school or child care group setting for 21 days. The Department proposes this expansion to include susceptible persons for consistency in requirements for severe, vaccine preventable diseases, such as diphtheria, measles and rubella. The Department proposes to define a person susceptible for varicella as a person who presents no history of an age-appropriate dose of varicella vaccination while 12 months of age or older, does not have a diagnosis of varicella disease as set forth in a written record from a health care practitioner acting within the scope of their practice, does not demonstrate serological evidence of varicella immunity (the presence of antibodies to rubella determined by an enzyme-linked immunosorbent assay test or a comparable test, and was born in the United States before 1980. *See* CDC. (2021). *Pink Book*, *Chapter 22: Varicella*, *14th ed*. Retrieved from https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-22-varicella.html (individuals born in the United States after 1980 are considered to have evidence of immunity except for health-

care personnel, pregnant individuals, and immunocompromised persons). The Department proposes this definition to clarify that exclusion would be appropriate under this paragraph only in circumstances when a person is able to transmit the disease to another, due to an incomplete or absent history of vaccination or lack of natural immunity, to prevent the possibility of an outbreak among those, such as children, who are most vulnerable to severe disease.

Subsection (b)

Existing § 27.153 (relating to restrictions on food handlers) and § 27.155 (relating to restrictions on health care practitioners) excludes persons with certain diseases, infections and conditions from working as food handlers and health care practitioners who provide direct care, until certain conditions have been met. The Department proposes, for clarity and readability, to move these requirements, with amendments described below, to this subsection so that exclusion and readmission requirements are all in one place. The Department proposes to also set forth the requirements in a chart format, consistent with other sections in the proposed regulations, for ease of readability.

The Department proposes to place the burden on supervisors of these individuals to adhere to these requirements, as supervisors are in the best position to ensure that exclusion and readmission requirements are being met. This proposed amendment is also consistent with existing § 27.71 and proposed § 27.71a, which places this same burden on supervisors in a school or child care group setting. The Department also proposes to extend the requirements from those who have the disease, infection or condition to those who are suspected of having it. This proposed amendment also aligns with the requirements for those in a school or child care group setting and is necessary to prevent transmission. The Department further proposes to extend the requirements to those who volunteer as food handlers or health care practitioners who

provide direct care, which aligns with the requirements for those in a school or child care group setting. This proposed amendment also clarifies that the requirements apply to everyone working as a food handler or health care practitioner, regardless of employment status, to reduce the risk of transmission. Lastly, the Department does not propose to retain the existing exclusion requirements in §§ 27.153 and 27.155 for persistent diarrhea. Persistent diarrhea is a symptom only and may not necessarily be indicative of disease that warrants exclusion.

Amebiasis

Existing § 27.153 and § 27.155 excludes persons, with amebiasis, from working as food handlers and health care practitioners who provide direct care until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician; if an antiparasitic treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. Existing § 27.156 extends this requirement to household contacts who prepare or serve food or provide direct patient care. The Department proposes to retain this exclusion for food handlers, health care practitioners, and household contacts, but to require "two consecutive negative tool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as an ova and parasite exam. If antiparasitic treatment has been given, the specimens may not be collected until 48 hours after the last dose of treatment was taken." The Department proposes that the test utilized for the negative stool specimens be an ova and parasite exam or a test deemed acceptable to the Department. An ova and parasite exam looks for ova or eggs of parasites. *See* CDC. (April 9, 2024). Diagnosis of Parasitic Disease. Retrieved from https://www.cdc.gov/parasites/testing-diagnosis/index.html. Allowing other tests deemed acceptable to the Department permits for new or alternative tests to also be utilized for testing.

Hepatitis A and E or jaundice without a known etiology

Existing § 27.153 and § 27.155 excludes persons, with hepatitis A, viral hepatitis or jaundice of unspecified etiology, from working as food handlers and health care practitioners who provide direct care until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician. The Department proposes to retain this exclusion for food handlers, health care practitioners, and household contacts, but to rephrase it for readability. The Department also proposes to replace "viral hepatitis" with "hepatitis E" as hepatitis A and E present with similar symptoms. *See* Johns Hopkins Medicine. (2024). Hepatitis A and E. Retrieved from https://www.hopkinsmedicine.org/health/conditions-and-diseases/hepatitis/hepatitis-a.

Shiga toxin-producing Escherichia coli (i.e., STEC)

Existing § 27.153 and § 27.155 excludes persons, with enterohemorrhagic E. coli, from working as food handlers and health care practitioners who provide direct care until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician; if antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. Existing § 27.157 extends this requirement to household contacts who prepare or serve food or provide direct patient care. The Department proposes to retain this exclusion for food handlers, health care practitioners, and household contacts, but to refer to "enterohemorrhagic E. coli" as "Shiga toxin-producing Escherichia coli (*i.e.*, STEC)" as this is the more commonly known term for enterohemorrhagic E. coli. The Department proposes to add that the negative stool specimens must be by a test deemed acceptable to the Department, such as a culture or culture-independent diagnostic test and verified by an appropriate clinical laboratory instead of a physician. The

Department proposes throughout to require verification by a clinical laboratory instead of a physician, as a clinical laboratory is the most appropriate entity to verify test results.

The Department also proposes throughout to clarify that laboratory testing may be conducted using either a culture or culture-independent diagnostic test. Culture-independent diagnostic tests can detect the presence of a gene or antigen associated with a specific pathogen, can be conducted more rapidly and yield results far sooner than traditional culture-based methods, and are widely used by clinical laboratories. CDC. (2024). Foodborne Illness and Culture-Independent Diagnostic Tests. Retrieved from https://www.cdc.gov/foodnet/reports/cidt.html. Allowing other tests deemed acceptable to the Department, in addition to culture or culture-independent diagnostic tests permits for new or alternative tests to also be utilized for testing.

Shigellosis

Existing § 27.153 and § 27.155 excludes persons, with shigellosis, from working as food handlers and health care practitioners who provide direct care until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician; if antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. Existing § 27.158 extends this requirement to household contacts who prepare or serve food or provide direct patient care. The Department proposes to retain this exclusion for food handlers, health care practitioners, and household contacts. The Department proposes to add that the negative stool specimens must be by a test deemed acceptable by the Department such as a culture or culture-independent diagnostic test to the Department and verified by an appropriate clinical laboratory instead of a

physician. The Department proposes throughout to require verification by a clinical laboratory instead of a physician, as a clinical laboratory is the most appropriate entity to verify test results.

The Department also proposes throughout to clarify that laboratory testing may be conducted using either a culture or culture-independent diagnostic test. Culture-independent diagnostic tests can detect the presence of a gene or antigen associated with a specific pathogen, can be conducted more rapidly and yield results far sooner than traditional culture-based methods, and are widely used by clinical laboratories. CDC. (2024). Foodborne Illness and Culture-Independent Diagnostic Tests. Retrieved from https://www.cdc.gov/foodnet/reports/cidt.html. Allowing other tests deemed acceptable to the Department, in addition to culture or culture-independent diagnostic tests permits for new or alternative tests to also be utilized for testing.

Streptococcal infection (including strep throat)

The proposed addition of streptococcal infection (including strep throat) is new. The Department proposes to exclude a person with streptococcal infection from working or volunteering as a health care practitioner or food handler until they have completed 12 hours of antibiotic treatment as prescribed by a health care practitioner acting within the scope of their practice. This proposed requirement aligns with the proposed requirement for school, college, university and child care group settings.

A 2006 study from the University of Wisconsin found *Streptococcus pyogenes*, the etiologic agent of streptococcal infections, to have survived on several packaged food products and food contact surfaces, highlighting the importance of excluding persons with streptococcal respiratory infections from working or volunteering as food handlers, in order to prevent the spread of infection. Ingham, S. et al. (2005). "Survival of Streptococcus pyogenes on Foods

and Food Contact Surfaces." *J. Food Protect*., 69(5). Retrieved from https://www.sciencedirect.com/science/article/pii/S0362028X22074336?via%3Dihub. Additionally, group A streptococcus (*Streptococcus pyogenes)*, is a contagious illness spread through respiratory droplets, and can cause streptococcal toxic shock syndrome, a rare but severe infection of an individual's bloodstream or deep tissues, which can be fatal. *See* CDC. (2024). Clinical Guidance for Streptococcal Toxic Shock Syndrome. Retrieved from https://www.cdc.gov/group-a-strep/hcp/clinical-guidance/streptococcal-toxic-shock-syndrome.html. Given this risk, the Department proposes to require that health care practitioners be excluded as well until 12 hours of antibiotic treatment has been completed.

Typhoid fever or paratyphoid fever

Existing § 27.153 and § 27.155 excludes persons, with typhoid fever or paratyphoid fever, from working as food handlers and health care practitioners who provide direct care until the etiologic organism has been eradicated as proven by three negative successive stool specimens collected at intervals of at least 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. The Department proposes to retain this exclusion in subparagraph (i) but to specify 30 days instead of 1 month, as the number of days within a month may vary

Existing § 27.159 extends exclusion to household contacts and chronic carriers who prepare or serve food or provide direct patient care. Existing § 27.159(a) and (b) excludes asymptomatic and symptomatic household contacts until the contact had submitted two stool specimens, taken at least 24 hours apart, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Salmonella

typhi or Salmonella paratyphi. The Department proposes to retain this exclusion in subparagraph (ii) that is the same for both asymptomatic and symptomatic contacts, except that symptomatic household contacts must have specimens collected no earlier than 30 days after onset of symptoms, instead of 1 month, as the number of days within a month may vary . Existing § 27.159(c) excludes chronic carriers until three consecutive negative fecal cultures are obtained from specimens taken at least 1 month apart and at least 48 hours after antibiotic therapy has stopped. The Department proposes to retain this exclusion in subparagraph (ii) but specify 30 days instead of 1 month, as the number of days within a month may vary.

§ 27.72. Exclusion of children, students, staff and other persons having direct contact with children and students, for showing symptoms.

The Department proposes to rename the title of this section from "exclusion of students and persons having contact with students, for showing symptoms" to "exclusion of children, students, staff and other persons having direct contact with children and students, for showing symptoms" to clarify that this section applies not only to children in child care group settings but also students and other persons who have direct contact with children and students.

Subsection (a)

The Department proposes to rephrase the existing language in this subsection by replacing the words "public, private, parochial, Sunday or other school or college" with the words "school, college, university or child care group setting" and to simply refer to a "person" rather than a child, or staff person, including a volunteer." The Department also proposes to replace the requirement for a determination by a school nurse or a physician that the person's disease, infection, or condition is noncommunicable, with a requirement for a determination by a "health care practitioner acting within the scope of their practice" that "the symptom is not due to

an infectious cause." The Department proposes these amendments for clarity and readability and consistency with phrasing throughout the proposed regulations.

The Department does not propose any amendments to paragraph (1). In paragraph (2), the Department proposes to add the words "rash with" before the words "behavioral change" for clarity. The Department, in paragraph (3), proposes to delete the words "from the eyes" as discharge could occur from areas other than the eyes. The Department does not propose any amendments to paragraph (4). In paragraph (5), the Department proposes to replace the words "oral or axillary temperature equal to or greater than 102° F" with the words "a rectal, ear or forehead temperature of 100.4°F or higher; an oral or mouth temperature of 100°F or higher; or an under the arm temperature of 99°F or higher." This proposed amendment aligns with the AAP, which defines a fever in the same manner. *See* Schmitt, B.D. (2017). My Child Is Sick! Expert Advice for Managing Common Illnesses and Injuries, 2nd ed. Elks Village, IL: AAP, p. 15. In paragraph (6), the Department proposes to replace the words "unusual lethargy, irritability, persistent crying, difficulty breathing or other signs of severe illness" with the words "difficulty breathing suspected to be due to a communicable disease" to be more specific as lethargy, irritability, persistent crying and difficulty breathing, in of itself, is not necessarily indicative of a communicable disease.

The Department proposes, in paragraph (7), to replace the words "persistent vomiting" with the words "refractory (resistant to treatment) vomiting or diarrhea" and in paragraph (8) to delete the words "persistent diarrhea." The word "persistent" is highly subjective and could include many conditions which do not warrant exclusion, such as side effects of certain medications. On the other hand, vomiting or diarrhea that is resistant to treatment could be indicative of a communicable disease or infection, which would warrant exclusion.

In new, proposed paragraph (9), the Department proposes to add the words "draining wounds unless the wound is adequately covered." Several conditions, such as MRSA, can result in draining wounds, containing bacteria that can spread to others through direct contact. In new, proposed paragraph (10), the Department proposes to add diarrhea generally, unless due to a disease or condition requiring special measures, as specified in § 27.71a(a). The Department proposes this amendment because diarrhea can easily and rapidly spread, particularly in child care group settings, from one child to another. In new, proposed paragraph (11), the Department proposes to add a catch-all provision for "other signs of severe illness or known exposure to a communicable disease." Clear signs of severe illness could be indicative of a communicable disease, which could place others at risk of infection. Likewise, exposure to a communicable disease could place others at risk for infection.

Subsection (b)

The Department proposes to add the words "college or university, or child care provider" to clarify that the requirement in this subsection, like the requirements for exclusion in subsection (a), apply to schools, colleges, universities and child care providers.

§ 27.73. Readmission of excluded children, and staff having contact with children.

The Department proposes to delete this section, which prohibits a child or staff person, including a volunteer, having contact with children from being readmitted until in subsection (a), a school nurse or a physician is "satisfied that the condition for which the person was excluded is not communicable or until the person presents a statement from a physician that the person has recovered or is noninfectious" and in subsection (b), "a physician has determined the illness to be either resolved, noncommunicable or in a noncommunicable stage." The proposed amendment to § 27.72 (relating to exclusion of children, students, staff and other persons having direct

contact with children and students, for showing symptoms" to require exclusion "until a health care practitioner acting within the scope of their practice determines that the symptom is not due to an infectious cause" renders this section unnecessary.

§ 27.74. Readmission of isolated or quarantined students in a school, college or university, children in a child care group setting and persons having direct contact with students in a school, college or university or children in a child care group setting.

The Department proposes to rename the title of this section from "readmission of exposed or isolated children, and staff having contact with children" to "readmission of students in a school, college or university, children in a child care group setting and persons having direct contact with students in a school, college or university or children in a child care group setting who are in isolation or quarantine" to reflect the inclusion of these individuals in the proposed amendments to this section. The Department proposes to rephrase the existing language, requiring permission of "the LMRO" for a close contact who has been absent from being readmitted to school, to state that a person directed by the Department or local health department to be in isolation or quarantine can only be readmitted with permission of the Department or local health department. As indicated elsewhere, the term "LMRO" is outdated. In practice, cases are reported to either the Department or a local health department.

§ 27.75. Exclusion of children, and staff having contact with children, during a measles outbreak.

The Department proposes to delete this section, which currently requires that children, and staff, including volunteers, having contact with children be excluded from school during a measles outbreak under the procedures in existing § 27.160 (relating to special requirements for measles). As discussed previously, the Department proposes to move exclusion and readmission

requirements to proposed § 27.71a. These requirements would encompass the exclusion and readmission of individuals when there is a measles outbreak. This section is therefore no longer necessary.

§ 27.76. Exclusion and readmission of children, and staff having contact with children, in child care group settings.

The Department proposes to delete this section, which currently sets forth exclusion and readmission requirements for specific diseases, infections and conditions for children, and staff having contact with children, in child care group settings. As discussed previously, the Department proposes to move exclusion and readmission requirements to proposed § 27.71a, which includes, as discussed in that section, the requirements set forth in this section. This section is therefore no longer necessary.

§ 27.77. Immunization requirements for children in child care group settings.

Subsection (a)

The Department proposes to delete the words "effective March 27, 2002." Anyone who was a child in 2002 has since reached the age of majority, and therefore, this language is no longer necessary. The Department, in paragraph (1), proposes to add "or on the basis of a strong moral objection or ethical conviction similar to a religious belief" to the grounds upon which a parent or guardian may object to a child being vaccinated. A stakeholder expressed that "on the basis of a strong moral or ethical conviction similar to a religious belief" is not necessary as a parent or guardian can already object to a child being vaccinated on a religious grounds which they believe to be sufficient. The Department has chosen to keep the proposed addition of "or on the basis of a strong moral objection or ethical conviction similar to a religious belief" because it is consistent with other existing regulations, that permit exemptions to requirements for

vaccinations for school-age children at 28 Pa. Code § 23.84 (relating to exemption from immunization) and child care centers at 55 Pa. Code § 3270.131 (relating to health information). Specifically, under 28 Pa. Code § 23.84(b), children do not need to be immunized if the parent, guardian or emancipated child objects in writing to the immunization on religious grounds or on the basis of a strong moral or ethical conviction similar to a religious belief. Similarly, 55 Pa. Code § 3270.131(e)(2)(i) permits exemption based on religious belief or strong personal objection equated to a religious belief, as documented in a written, signed and dated statement from the child's parent or guardian.

In subparagraph (i), the Department proposes to replace the word "physician" with the words "health care practitioner acting within the scope of their practice" for consistency in the use of this terminology throughout the proposed regulations. The Department proposes to replace the words "any vaccines recommended by ACIP" with the words "each of the vaccines listed in subsection (b)." The Department proposes to include specific vaccinations in regulation rather than deferring to recommendations from ACIP, to provide clarity and certainty to the regulated community. The Department also proposes to replace the word "any" with the word "each" and to add the word "a" before the words "medical condition." The Department proposes these amendments for grammar and clarity.

In subparagraph (ii), the Department proposes to replace the word "physician" with the words "health care practitioner acting within the scope of their practice" for consistency in the use of this terminology throughout the proposed regulations. The Department also proposes a grammatical clarification with the addition of the words "shall be submitted" to make it clear that subsequent written verifications for additional vaccinations as they become due are required to

be submitted to the caregiver. The Department proposes to add the words "subsequent written" before the word "verifications" in the next two sentences for clarity.

The Department proposes in paragraph (2), to replace the word "physician" with the words "health care practitioner acting within the scope of their practice" for consistency in the use of this terminology throughout the proposed regulations. The Department does not propose any amendments to paragraph (3). In paragraph (4), the Department proposes to delete the requirement that the immunization status of each enrolled child be summarized and reported to the Department on an annual basis. The Department proposes to replace this requirement with a requirement for the caregiver to provide immunization status to the Department "upon request" and to add language that would permit the Department to review the immunization status of a child at the caregiver's location and to provide the caregiver with on-site immunization education. These proposed amendments not only reflect the Department's current practice but are necessary for the Department to effectively conduct investigations as vaccination status is an indicator as to which children are susceptible and may need to be quarantined in cases of illness or disease.

Subsection (b)

The Department proposes to amend the title in this subsection from "vaccination requirements" to "immunity requirements." This proposed amendment more accurately reflects the substantive provisions of this subsection, which require that children enrolled in child care group settings be "immunized" against certain diseases, infections and conditions, and recognizes that immunity can occur through methods other than vaccination, as reflected by the Department's proposed amendment in new, proposed subsection (b.1). The Department also proposes to delete language requiring that children be immunized in accordance with ACIP

recommendations, which are currently outlined in paragraphs (1) and (2). The Department proposes, instead for clarity, to add language requiring that children be immunized against certain diseases, as set forth in paragraphs (3) through (15) and verified by a health care practitioner acting within their scope of practice. The proposed immunization requirements are as follows: diphtheria by age 6; haemophilus influenzae type b by 4 months of age; hepatitis A by 18 months of age; hepatitis B by 18 months of age; measles by age 6; mumps by age 6; pertussis by age 6; pneumococcal disease by 15 months of age; poliovirus by age 6; rotavirus by 6 months of age; rubella by age 6; tetanus by age 6; and varicella (chickenpox) by 15 months of age. This aligns generally with current American Academy of Pediatrics' (AAP) recommendations as well as existing immunization requirements in 28 Pa. Code § 23.83 (relating to immunization requirements) for school-aged children. *See* AAP. (2026). Recommended Child and Adolescent Immunization Schedule. Retrieved from https://downloads.aap.org/AAP/PDF/AAP-Immunization-Schedule.pdf. The Department proposes these amendments to align with evidence-based recommendations made by the nation's leading medical associations, in accordance with Executive Order 2025-02 – Protecting Pennsylvanians' Health and Freedom by Ensuring Access to Safe and Effective Vaccines. *See* Executive Order Commonwealth of Pennsylvania Governor's Office. (October 1, 2025). Executive Order 2025-02 – Protecting Pennsylvanians' Health and Freedom by Ensuring Access to safe and Effective Vaccines. Retrieved from https://www.pa.gov/content/dam/copapwp-pagov/en/oa/documents/policies/eo/2025-02.pdf.

Some stakeholders expressed concerns regarding the deletion of the incorporation by reference of the ACIP recommendations in this section. However, this amendment is necessary as the Department is not permitted to delegate its authority to make rules and regulations by

adopting future recommendations. *See Protz v. Workers' Compensation Appeal Board*, 161 A.3d 827 (Pa. 2017) (holding that a provision in the Workers' Compensation Act, requiring a physician to apply the methodology set forth in the most recent version of the American Medical Association Guides to the Evaluation of Permanent Impairment, was an unconstitutional delegation of legislative authority).

Subsection (b.1)

The Department proposes to define the term "immunized" for the purposes of this section, as "a person that is protected against a disease through multi-dose vaccination at appropriate intervals or natural immunity to the extent that a health care practitioner determines the person to have sufficient levels of antibodies to be exposed to the disease without becoming infected." This proposed definition aligns generally with the CDC, which defines active immunity as natural immunity acquired from exposure through infection with the actual disease and vaccine-induced immunity acquired through the introduction of a killed or weakened form of the disease organism through vaccination. *See* CDC. (2024). Immunity Types. Retrieved from https://www.cdc.gov/vaccines/basics/immunity-types.html.

Subsection (c)

The Department proposes to delete this subsection, which presently permits the Department to update the list of requirements through adoption of ACIP recommendations in a notice published in the *Pennsylvania Bulletin*. The Department does not have authority to update the list of required immunizations in this manner.

Subsection (e)

The Department proposes to delete the cross-reference to existing § 27.76 (relating to exclusion and readmission of children, and staff having contact with children, in child care group

settings). As indicated previously, the Department proposes to delete this section and to place exclusion and readmission requirements in proposed § 27.71a. The Department proposes to replace the cross-reference to § 27.76 with a cross-reference to § 27.71a.

Subchapter D. Sexually Transmitted Diseases, Tuberculosis and Other Communicable Diseases

§ 27.81. Examination of persons suspected of being infected.

The Department proposes, in the last sentence of this section, to replace the words "an LMRO" with "a local health department." As noted elsewhere in this preamble, the Department proposes to delete the term LMRO and replace all references to the LMRO with "local health department." The term "LMRO" is outdated. In practice, cases are reported to either the Department or a local health department. The Department proposes to replace the term "LMRO" with "local health department" where it appears throughout the regulations.

§ 27.83. Court ordered examinations.

The Department proposes in the last sentence of this section to replace "local health authority or the Department on case report forms furnished by the Department" with "Department's electronic disease surveillance system." This proposed amendment reflects the current practice of reporting test results for sexually transmitted diseases electronically through the Department's electronic disease surveillance system rather than through a form.

§ 27.84. Examination for a sexually transmitted disease of persons detained by police authorities.

The Department proposes one minor amendment to this section. In subsection (b), the Department proposes to delete the word "reformatory" as this is an outdated term that is no longer used.

§ 27.85. Confidential diagnosis and treatment of a sexually transmitted disease.

The Department proposes to add the word "confidential" before the words "diagnosis" and "treatment" throughout this section, including the title. This proposed amendment reflects the Department's current practice of treating all diagnosis and treatment of sexually transmitted diseases as confidential.

§ 27.87. Refusal to submit to treatment for communicable diseases.

The Department proposes, in subsection (a)(ii), to replace the words "an LMRO" with the words "a local health department" for consistency in terminology. The Department proposes to delete subsection (c), which currently provides that for the purposes of this section, treatment approved by the Department may include treatment by an accredited practitioner of a well-recognized church or religious denomination which relies on prayer or spiritual means alone for healing, if requirements relating to sanitation, isolation or quarantine are satisfied. The Department proposes this amendment for clarity. In practice, the Department relies on evidence-based treatments and would only approve of a church, religious or spiritual treatment to the extent that it is evidence-based.

§ 27.89. Examinations for syphilis.

Subsection (a)

In paragraph (1)(i), the Department proposes to replace the words "physician who" with "health care practitioner who within the scope of their practice" before the words "attends, treats

or examines." The Department proposes this amendment for consistency in the use of the broader term "health care practitioner" throughout the regulations.

In paragraph (1)(ii), the Department proposes to delete the requirement for a physician to collect and test a sample of a pregnant individual's blood during the third trimester of pregnancy in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate that is occurring in a given population which the CDC has determined it cost-effective to require special precautions. The Department proposes to replace this requirement for all pregnant individuals to receive this testing during the third trimester of pregnancy unless the individual objects. Due to a rise in cases of syphilis throughout this Commonwealth, the Department has determined that testing is necessary for all pregnant individuals in the third trimester. *See* CDC. (2025). Table 3. Total Syphilis – Reported Cases and Rates of Reported Cases by State/Territory and Region in Alphabetical Order, United States. Retrieved from https://www.cdc.gov/sti-statistics/media/pdfs/2025/09/2023_STI_Surveillance_Report_FINAL_508.pdf.

Similarly, the Department proposes to delete paragraph (1)(iii), which currently indicates that the Department will publish a list of counties in which the CDC has determined it is cost-effective to require special precautions. As noted previously, due to a rise in cases of syphilis throughout this Commonwealth, the Department has determined that testing is necessary for all pregnant individuals during the third trimester of pregnancy.

In paragraph (2), the Department proposes to replace the word "physician" with the words "health care practitioner" for consistency in terminology throughout the proposed regulations. The Department proposes to replace the words "the submission of a certificate by the physician that" with the word "if" before the words "the patient is unable to pay." The

Department does not presently require a certificate from a physician that a patient is unable to pay.

Subsection (b)

The Department proposes to delete the words "in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions" and the language in paragraph (1) indicating that a list of these counties will be published in the *Pennsylvania Bulletin*. Due to rising cases of syphilis throughout this Commonwealth, the Department has determined that it is necessary to test all newborns.

Subsection (c)

The Department proposes to delete the words "delivered in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions" and the language in paragraph (i) indicating that a list of these counties will be published in the *Pennsylvania Bulletin*. Due to rising cases of syphilis throughout this Commonwealth, the Department has determined that it is necessary to test all stillborn infants. The Department also proposes to delete paragraph (iii) which indicates that the Department will be responsible for alerting physicians about this standard as superfluous and unnecessary.

§ 27.95. Reporting syphilis examination information for births and fetal deaths.

The Department proposes to replace the words "physicians and others required to make the reports" with the words "health care practitioners." The Department proposes this amendment for consistency in the use of the broader term "health care practitioner" throughout the proposed regulations.

§ 27.96. Diagnostic tests for sexually transmitted diseases.

The Department proposes, in subsection (a), to replace the words "Food and Drug Administration" with the acronym "FDA" for consistency in the use of this term, as it is defined in existing and proposed § 27.1 of the regulations. The Department proposes, in subsection (b), to replace the words "Division of Clinical Microbiology" with the word "Department's" before the words "Bureau of Laboratories." The Department proposes this amendment as division names within the Department are subject to change over time.

§ 27.98. Prophylactic treatment of newborns.

Subsection (a)

The Department proposes to replace the words "physicians and midwives attending women" with the words "a health care practitioner acting within the scope of their practice who attends individuals" before the words "in childbirth." The Department proposes this amendment for consistency in the use of the broader term "health care practitioner" throughout the regulations. The Department also proposes a grammatical clarification with the addition of the word "other" before the words "appropriate medication" to clarify that the medication used for prophylactic treatment of newborns could include a medication that is not listed in the regulation.

Subsections (b) and (c)

The Department proposes to replace the word "physician" with the words "health care practitioner." The Department proposes this amendment for consistency in the use of the broader term "health care practitioner" throughout the regulations.

§ 27.99. Prenatal examination for hepatitis B.

The Department proposes to replace the word "physician" with the words "health care practitioner acting within the scope of their practice" throughout this section for consistency in

terminology. The Department proposes to replace the words "clinical laboratory approved by the Department to conduct immunologic testing" with "laboratory authorized to conduct testing for hepatitis B under applicable State and Federal law" to account for laboratories outside of this Commonwealth that may process specimens within applicable State and Federal law requirements. Additionally, there are now other types of testing for hepatitis B than just immunologic testing. While immunologic testing is still used, the CDC recommends the use of the triple panel test, which includes testing for HBsAg, Anti-HBs, and total antibody to hepatis B core antigen (total anti-HBc). CDC. (2025). Clinical Testing and Diagnosis for Hepatitis B. Retrieved from https://www.cdc.gov/hepatitis-b/hcp/diagnosis-testing/index.html.

§ 27.99a. Prenatal examination for hepatitis C.

This proposed section is new. The Department proposes, in subsection (a), to require a health care practitioner acting within their scope of practice to take a blood sample, unless the individual objects, of a pregnant individual at the time of the first examination or within 15 days, but no later than the time of delivery, and to submit the sample to a laboratory authorized to conduct testing for hepatitis C under applicable State and Federal law. The Department proposes, in subsection (b), to require the health care practitioner to refer the birthing individual and the infant to appropriate follow-up care, when a pregnant individual tests positive for hepatitis C ribonucleic acid. The hepatitis C virus can be transmitted to the fetus and newborn during pregnancy and delivery. If the pregnant individual has hepatitis C, they can be treated with direct-acting antiviral therapy to reduce the risk of transmission to the fetus or newborn. The CDC also recommends hepatitis C screening in all individuals 18 years or older and pregnant individuals. CDC. (2025). Clinical Screening and Diagnosis for Hepatitis C. Retrieved from https://www.cdc.gov/hepatitis-c/hcp/diagnosis-testing/index.html.

§ 27.99b. Prenatal examination for HIV.

This proposed section is new, and similar to proposed § 27.99a (relating to prenatal examination for hepatitis C), will require a health care practitioner acting within the scope of their practice to take a blood sample, unless the individual objects, from a pregnant individual at the time of the first examination or within the first trimester and the third trimester but no later than the time of delivery, and to submit the sample to a laboratory authorized to conduct testing for HIV under applicable State and Federal law. The Department proposes this amendment to align with the CDC, who recommends that all pregnant individuals be tested for HIV as early as possible, preferably at the first prenatal visit. CDC. (2024). HIV, Viral Hepatitis, STD & Tuberculosis Prevention in Pregnancy. Retrieved from https://www.cdc.gov/pregnancy-hiv-std-tb-hepatitis/about/index.html. Similar to hepatitis C, the earlier HIV is diagnosed and treated, the more effective HIV medicines can be at preventing transmission and improving the health outcomes of both the individual and child. *Id.*

Subchapter E. Selected Procedures for Preventing Disease Transmission

§ 27.151. Restrictions on the donation of blood, blood products, tissue, sperm and ova.

The Department proposes to delete this section, which places restrictions on the donation of blood, blood products, tissues, sperm and ova, because these areas fall within the purview of the FDA. Specifically, the FDA regulates human cells or tissue, including reproductive tissue (sperm and eggs). *See* 12 CFR Part 1271 (relating to human cells, tissues, and cellular and tissue-based products). The FDA is also responsible for ensuring the safety of the nation's blood supply. *See* 21 CFR Part 630 (relating to requirements for blood and blood components intended for transfusion or for further manufacturing use).

§ 27.152. Investigation of cases and outbreaks.

The Department proposes to delete this section. The Department proposes to move the requirements in this section to proposed §§ 27.60a and 27.60e, with amendments, as explained in those sections.

§ 27.153. Restrictions on food handlers.

The Department proposes to delete this section, which currently sets forth restrictions for food handlers for specific diseases, infections and conditions. As discussed previously, the Department proposes to move exclusion and readmission requirements to proposed § 27.71a, which includes, as discussed in that section, the requirements set forth in this section. This section is therefore no longer necessary.

§ 27.154. Restrictions on caregivers in a child care group setting.

The Department proposes to delete this section, which currently sets forth restrictions for caregivers in a child care group setting for specific diseases, infections and conditions. As discussed previously, the Department proposes to move exclusion and readmission requirements to proposed § 27.71a, which includes, as discussed in that section, the requirements set forth in this section. This section is therefore no longer necessary.

§ 27.155. Restrictions on health care practitioners.

The Department proposes to delete this section, which currently sets forth restrictions on health care practitioners for specific diseases, infections and conditions. As discussed previously, the Department proposes to move exclusion and readmission requirements to proposed § 27.71a, which includes, as discussed in that section, the requirements set forth in this section. This section is therefore no longer necessary.

§ 27.156. Special requirements for amebiasis.

The Department proposes to delete this section, which currently sets forth special requirements for amebiasis. As discussed previously, the Department proposes to move these requirements to proposed § 27.71a. This section is therefore no longer necessary.

§ 27.157. Special requirements for enterohemorrhagic E. coli.

The Department proposes to delete this section, which currently sets forth special requirements for enterohemorrhagic E. coli. As discussed previously, the Department proposes to move these requirements to proposed § 27.71a. This section is therefore no longer necessary.

§ 27.158. Special requirements for shigellosis.

The Department proposes to delete this section, which currently sets forth special requirements for shigellosis. As discussed previously, the Department proposes to move these requirements to proposed § 27.71a. This section is therefore no longer necessary.

§ 27.159. Special requirements for typhoid and paratyphoid fever.

The Department proposes to delete this section, which currently sets forth special requirements for typhoid and paratyphoid fever. As discussed previously, the Department proposes to move these requirements to proposed § 27.71a. This section is therefore no longer necessary.

§ 27.160. Special requirements for measles.

The Department proposes to delete this section, which currently sets forth special requirements for measles. As discussed previously, the Department proposes to move these requirements to proposed § 27.71a. This section is therefore no longer necessary.

§ 27.161. Special requirements for tuberculosis.

Subsection (a)

The Department, in subsection (a)(2)(i), proposes to replace the words "and any updates thereto as approved by the Board" with the words "as published in the Morbidity and Mortality Weekly Report (December 30, 2005)." The Department also proposes to delete subsection (a)(2)(ii), which presently indicates that the Department will publish notice in the Pennsylvania Bulletin of any updates to this publication. The Department is not permitted to delegate its authority to make rules and regulations by adopting a private organization's future recommendations. *Protz*. The Department may, however, adopt a particular set of standards which are already in existence at the time of the adoption. *Id.*; *Pennsylvania AFL-CIO v. Commonwealth*, 219 A.3d 306 (Pa. Cmwlth. 2019). The Department proposes to adopt CDC *Guidelines for Preventing the Transmission of Mycobacterium in Tuberculosis in Health-Care Facilities*, as published in the Morbidity and Mortality Weekly Report (December 30, 2005). The Department will amend the regulations should future updates to this guidance be required.

Subsection (b)

The Department proposes to replace the words "Mantoux tuberculin test" with the words "tuberculosis screening test." Mantoux tuberculin test refers to a tuberculosis (TB) skin test. TB can also be tested for by a blood test called interferon-gamma release assays (IGRAs). The Department therefore proposes broader language to encompass all TB screening tests, which will permit a household or other close contact to be tested by either a TB skin test or blood test.

Subsection (c)

The Department proposes to require that a person with a suspected or confirmed case of TB be provided DOT until the person's course of treatment for suspected or confirmed TB is complete. Treatment for TB can take between 4 to 9 months, depending on the treatment regimen. CDC. (2025). Treatment for Drug-Susceptible Tuberculosis Disease. Retrieved from

https://www.cdc.gov/tb/hcp/treatment/tuberculosis-disease.html. It usually takes 6 months or longer for TB medications to kill all TB germs, even if a patient feels better, and stopping medication too soon can be dangerous. CDC. (2023). Questions and Answers About Tuberculosis Booklet. Retrieved from https://www.cdc.gov/tb/media/Question_Answers_About_TB_English.pdf. DOT is the best way to ensure adherence to treatment and is recommended for all TB patients. *Id*.

The Department proposes to require notification to the Department or local health department if DOT is provided and for the health care practitioner or provider to record all DOT visits. The Department further proposes to require that a health care practitioner or provider provide records of DOT to the Department or local health department, upon request. Treatment for tuberculosis may take 6 or more months, and to be effective, patients must maintain and complete medication and treatment regimens. DOT helps patients take the medication to finish the therapy as quickly as possible, reduces the risk of spread, decreases risk of drug-resistance resulting from erratic or incomplete treatment, and decreases the risk of treatment failure.

§ 27.162. Special requirements for animal bites, scratches or contamination of open wounds or mucous membranes.

The Department proposes to amend the title of this section to include "scratches or contamination of open wounds or mucous membranes." This proposed amendment reflects the proposed expansion of the requirements in this section to include animal "scratches or contamination of open wounds or mucous membranes."

The Department proposes to replace the words "a biting animal" with the words "an animal that has potentially exposed a human to rabies through a bite, scratch or contamination of an open wound or mucous membrane." As noted, this proposed addition expands the

requirements of this section to include not only animal bites but also scratches or contamination of an open wound or mucous membrane. The addition of "potentially exposed" further clarifies that the requirements would apply to any animal that may have exposed a human to rabies. Although rare, humans can get rabies from non-bite exposures such as scratches, abrasions, or open wounds that are exposed to saliva or other potentially infectious material, such as mucus from a rabid animal. CDC. (2024). How is Rabies Transmitted? Retrieved from https://www.cdc.gov/rabies/hcp/clinical-overview.

The Department does not propose any amendments to paragraph (1). In paragraph (2), the Department proposes to delete the word "or" and add the words "or ferret" after the word "cat." This expands the existing requirement to confine a healthy dog or cat for ten days to include healthy ferrets that bite or otherwise potentially expose a human to rabies. Young children are at a greater risk of bites from ferrets, and the CDC does not recommend ferrets in homes with children younger than 5 years of age. CDC. (2025). Ferrets. Retrieved from https://www.cdc.gov/healthy-pets/about/ferrets.html. The Department also proposes to replace the words "quarantined," "a quarantine" and "quarantine" with the words "confined" and "confinement" in paragraphs (2) and (3). The term "confinement" rather than "quarantine" more accurately reflects the period in which the animals identified in this section should be held and observed.

§ 27.163. Special requirements for psittacosis.

The Department proposes to delete this section. This section currently specifies that quarantine is not needed for a household contact of a bird with psittacosis, but that the parts of a building housing the infected birds are to be cleaned and disinfected before used by human beings. Psittacosis is a disease caused by a bacterium that infects birds and can cause mild

illness or pneumonia in humans. CDC. (2024). About Psittacosis. Retrieved from https://www.cdc.gov/psittacosis/about/index.html. Since 1988, there has been a decline in reported psittacosis cases. CDC. (2025). Psittacosis Surveillance and Trends. Retrieved from https://www.cdc.gov/psittacosis/php/surveillance/. Additionally, the Pennsylvania Department of Agriculture has authority over cases of "chlamydia (psittacosis)" under the Domestic Animal Law and is required to inform and consult with the Department regarding outbreaks that may threaten human health, including appropriate actions to take when there is an outbreak. *See* 23 Pa. C.S.A. § 2321(a) and (c) (relating to dangerous transmissible diseases). If needed, the Department could rely on its general authority under proposed Subchapter C to isolate or quarantine cases of psittacosis.

§ 27.164. Special requirements for close contacts of cases of plague, pharyngitis or pneumonia.

The Department proposes to delete this section, which requires a close contact of a person or animal diagnosed with plague, pharyngitis, or pneumonia to be provided chemoprophylaxis and placed under surveillance for 7 days. Knowledge and understanding of diseases, infections and conditions may change over time. Additionally, variants of diseases, infections and conditions can and do occur, resulting in the need for updated guidance. If needed, the Department could rely on its general authority under proposed Subchapter C to isolate or quarantine close contacts of these cases.

Subchapter F. Miscellaneous Provisions

Psittacosis

§ 27.181. Records of the sale, purchase or exchange of psittacine birds.

The Department proposes to delete this section which requires a dealer who purchases, sells or gives away a bird of the psittacine family to maintain a record for two years of each transaction. The Pennsylvania Department of Agriculture has authority over the quarantine of domestic animals, with dangerous transmissible diseases, which includes psittacosis, in this Commonwealth. *See* 3 Pa. C.S.A. § 2329; 3 Pa. C.S.A. § 2321. It is unlawful for any person to sell or remove an animal that is the subject of quarantine without approval of the Department of Agriculture. *See* 3 Pa. C.S.A. § 2329. Additionally, the Department of Agriculture is required to inform the Department of an outbreak of domestic animal disease which may threaten human health, and together, the Department and the Department of Agriculture are to determine the public health risk and the appropriate action to manage such risk. *See* 3 Pa. C.S.A. § 2321(c).

§ 27.182. Procurement of birds where psittacosis exists.

The Department proposes to delete this section, which prohibits procurement of birds from a source where psittacosis is known to exist. The Pennsylvania Department of Agriculture has authority over the quarantine of domestic animals, with dangerous transmissible diseases, which includes psittacosis, in this Commonwealth. *See* 3 Pa. C.S.A. § 2329; 3 Pa. C.S.A. § 2321. It is unlawful for any person to sell or remove an animal that is the subject of quarantine without approval of the Department of Agriculture. *See* 3 Pa. C.S.A. § 2329. Additionally, the Department of Agriculture is required to inform the Department of an outbreak of domestic animal disease which may threaten human health, and together, the Department and the Department of Agriculture are to determine the public health risk and the appropriate action to manage such risk. *See* 3 Pa. C.S.A. § 2321(c).

§ 27.183. Occurrence of psittacosis.

Subsection (a)

The Department proposes to delete "or avian family" from the subsection (a) from the requirement that a case of psittacosis in the avian family shall be cause for investigation. The Department proposes this deletion because the Pennsylvania Department of Agriculture has authority over the quarantine of domestic animals, with dangerous transmissible diseases, which includes psittacosis, in this Commonwealth. *See* 3 Pa. C.S.A. § 2329; 3 Pa. C.S.A. § 2321. The Department of Agriculture is required to inform the Department of an outbreak of domestic animal disease which may threaten human health, and together, the Department and the Department of Agriculture are to determine the public health risk and the appropriate action to manage such risk. *See* 3 Pa. C.S.A. § 2321(c). If needed, the Department could rely on its general authority under proposed Subchapter C to isolate or quarantine cases of psittacosis.

The Department proposes to replace the word "the" with the word "a" for grammatical purposes due to the proposed deletion of the words "or avian family." The Department also proposes to replace the word "LMRO" with the words "Department or local health department." As explained previously, the term "LMRO" is outdated, and the Department proposes to replace this term throughout the regulations with the more appropriate term, "local health department." The Department proposes to add the word "Department" as there may be circumstances, such as areas where there is not a local health department, when the Department may be the entity conducting the investigation of a case of psittacosis.

Subsection (b)

The Department proposes amendments, for grammatical reasons, to clarify the use of the term "quarantine" as it is defined in proposed § 27.1.

Subsection (c)

The Department proposes to delete subsection (c), which addresses the sale or removal of a bird with psittacosis, as the Department does not have authority over the sale or removal of quarantined animals. As noted previously, the Pennsylvania Department of Agriculture has authority over the quarantine of domestic animals, with dangerous transmissible diseases, which includes psittacosis. It is unlawful for any person to sell or remove an animal that is the subject of quarantine without approval of the Department of Agriculture. *See* 3 Pa. C.S.A. § 2329.

Restriction of Animals and Animal Products and Materials

The Department proposes to replace the word "importation" with the word "restriction" and to add "and materials" to the content header for animals and animal products. The Department proposes these amendments for consistency in terminology and other proposed amendments, as described in § 27.191 (relating to restriction of animals and animal products and materials to prevent a public health emergency and during a public health emergency), below.

§ 27.191. Restriction of animals and animal products and materials to prevent a public health emergency and during a public health emergency.

The Department proposes to replace the word "importation" with the word "restrictions" in the title of this section and to add "and materials to prevent a public health emergency and" before the words "during a public health emergency" to reflect the contents of this section more accurately. The Department proposes to replace the existing language in this section, which allows the Department to require a permit for animals or animal products in the event of a public health emergency. The Department has not implemented an animal permit process before and would have difficulty doing so during a public health emergency, when a process would likely need to be put into place immediately. The Department proposes, instead, language pertaining to the restriction of animals and animal products and materials, that would not require any type of

permitting process, and to extend this to not only include during a public health emergency, but to prevent one as well.

This proposed amendment is similar to current and proposed requirements pertaining to animals elsewhere in the proposed regulations. *See*, *e.g.*, §§ 27.61 (relating to isolation) and 27.65 (relating to quarantine), which provide for the quarantine and isolation of animals. The Department proposes to expand the restriction in § 27.191 to include not only animal products but also animal-related materials. The Department proposes to add a definition for animal products and animal-related materials to this section to clarify that the Department considers "animal products" and "animal-related materials" to include, but not be limited to "animal bedding, animal carcasses, animal feed, animal waste, equipment utilized for the care of animals, and food products made from animals" as these are the types of items that would most likely contain bacteria or other organisms that result in disease or illness.

The Department also proposes to add language to indicate that restriction may occur when animals and animal products and materials are "suspected or known to be contaminated by a pathogen that poses a threat to human health." The Department proposes this language to make clear the limited circumstances in which the Department would exercise this authority. When not related to a public health emergency, the U.S. Food and Drug Administration enforces the Federal Food, Drug, and Cosmetic Act and other related laws to product consumer's health and safety. The Pennsylvania Department of Agriculture also ensures compliance with food safety laws and regulations through its Bureau of Food Safety and Laboratory Services.

§ 27.192. Importation and sale of live turtles.

The Department proposes to delete this section, which currently addresses the sale or distribution of live turtles and requires that the seller or distributor of the turtles warrant to the

satisfaction of the Department that the shipment is free from salmonella contamination. The sale and distribution of live turtles is covered by Federal regulation. Specifically, the Federal government prohibits the sale of viable turtle eggs and live turtles with a carapace length of less than 4 inches. *See* 21 CFR 1240.62 (relating to turtles intrastate and interstate requirements). These smaller turtles cause the most illnesses and are especially risky to children, who are more likely to handle them and get sick. CDC. (2024). *Salmonella* Outbreak Linked to Small Turtles – August 2024. Retrieved from https://www.cdc.gov/salmonella/outbreaks/turtles-08-24/index.html. Because the Federal government has addressed the health risk associated with these turtles by banning their sale in the United States, the Department does not deem it necessary to retain a requirement in regulation pertaining to the sale and distribution of turtles.

Disposition of Effects and Remains of Infected Persons

§ 27.201. Disposition of articles exposed to contamination.

The Department proposes to delete the words "bedding, clothing, rags or other" before the word "articles" to make it clear that cleaning applies to all "articles" that have been exposed to contamination, not just bedding, clothing or rags. The Department also proposes to replace the words "bubonic plague, smallpox (variola, varioloid) or anthrax" with the words "a select agent or toxin." As defined in proposed § 27.1, a select agent or toxin is "biological material that has the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products, as determined by the DHHS and the USDA" under 7 CFR 331.1, 9 CFR 121.3 and 121.4 and 42 CFR 73.3. Select agents or toxins include yersinia pestis, the bacterium that causes plague; variola major virus (smallpox virus); and bacillus anthracis, the bacterium that causes anthrax, in addition to other agents or toxins as specified by the DHHS and USDA. The Department proposes to expand the current requirements to include all select agents

or toxins specified by the DHHS and USDA because all these select agents or toxins pose a significant threat to public health and therefore require the same measures to protect public health.

§ 27.202. Lease of premises exposed to a select agent or toxin.

The Department proposes to replace the words "occupied by a person with a communicable disease" with the words "exposed to a select agent or toxin" in the title of this section. The Department also proposes in the contents of the section to replace the words "in which there has been a person suffering from a communicable disease" with the words "that has been exposed to contamination from a select agent or toxin." Not all communicable diseases pose a significant threat to public health. However, all select agents and toxins do pose a significant threat to public health, and therefore, would require special measures, as identified in this section, to be taken to protect public health.

§ 27.203. Preparation for burial or transportation of deceased human bodies.

The Department proposes to rephrase the requirements in this section, pertaining to the preparation for burial or transportation of deceased human bodies. The existing regulation requires thorough disinfection of a body of a person who has died of specific communicable diseases by arterial and cavity injection with approved disinfectant fluid, washing of the body with an efficient germicidal solution, and plugging of body orifices. The Department proposes, in new subsection (a), to apply these requirements to all bodies of persons who have died of a communicable disease, except as provided for in subsection (b). The existing requirements to disinfect the body by arterial and cavity injection with approved disinfectant fluid, to wash the surface of the body with an efficient germicidal solution, and to plug the body orifices have been separated for readability purposes into subsections (1), (2), and (3), respectively.

The Department proposes, in new subsection (b), to require special handling for the body of a person who has died of smallpox or a viral hemorrhagic fever, including Ebola or Marburg, which can be transmitted in postmortem care settings through splashes of blood or other body fluids to unprotected mucosa. The Department proposes that the bodies of these persons only be handled as minimally necessary by a person in personal protective equipment and that they are not washed, cleaned or embalmed. In addition, the burial method must be cremation, or if cremation is not possible, the body must be buried in a standard metal casket. Bodies with smallpox and hemorrhagic fever virus are to be cremated without embalming. Only when cremation is not an option should the body be properly sealed in a container. These proposed requirements align with the CDC. *See* CDC. (2022). Safe Handling of Human Remains of VHF Patients in U.S. Hospitals and Mortuaries. Retrieved from hhttps://www.cdc.gov/viral-hemorrhagic-fevers/hcp/infection-control/guidance-for-safe-handling-of-human-remains-of-vhf-patients-in-u-s-hospitals-and-mortuaries.html; and CDC (2004). Morbidity and Mortality Weekly Report. Medical Examiners, Coroners, and Biologic Terrorism. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5308a1.htm.

§ 27.204. Funeral services.

The Department proposes to replace the words "in connection with the funeral" with the words "with the body" before the words "of a person who has died" to clarify that the requirements in this section apply when there is a body, and not when the person has been cremated. The Department proposes also to replace the words "with a disease for which isolation or quarantine is required" with "of anthrax, Creutzfeldt-Jakob disease, invasive group A streptococcal infection, plague, rabies, smallpox, yellow fever, viral hemorrhagic fever, including Ebola or Marburg, viral hepatitis, or other known or suspected communicable disease

associated with a public health emergency" to describe when the funeral services of a person who has died shall be private when ordered by the Department or local health authority. The Department proposes to replace the more general language with specific language for clarity. The Department proposes to add these specific diseases to align with recommendations from experts who advise bagging the person's body in a leak-proof plastic body bag, and to not allow the bereaved to see, touch or spend time with the body. *See* Hoffman, P.N. and Healing, T.D. (2022). The Infection Hazards of Human Cadavers. Retrieved from https://pubmed.ncbi.nlm.nih.gov/7749455/.

The Department also proposes to replace the words "an LMRO" with "a local health department." As noted previously, the term "LMRO" is outdated, and the Department proposes to replace the term "LMRO" with "local health department" throughout the regulations. Finally, in the last sentence, the Department proposes to replace the word "the" at the beginning of the sentence with "unless the order of the Department or local health department states otherwise" to reflect that the Department and local health department may increase or decrease the attendance for a funeral. This flexibility is necessary as viruses are constantly changing over time, resulting in new variants that can spread quickly, and in cases of death, the Department may need to restrict attendance to prevent the spread of disease. The proposed addition to permit "the officiating person" at a private funeral is also new and reflects the importance for a family to have an officiating person in attendance to lead any services provided and to comfort and support the family.

Fiscal Impact

Health care practitioners and health care facilities

Over 400,000 health care practitioners and over 6,000 health care facilities in this Commonwealth will be impacted by the proposed rulemaking. These practitioners and facilities will be positively impacted by proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable diseases, infections and conditions in proposed § 27.21a, which will make it easier for these practitioners and facilities to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All health care practitioners and health care facilities will be financially impacted by proposed amendments to § 27.21a, which will increase the number of diseases, infections and conditions that practitioners and facilities will have to report to the Department's electronic disease surveillance system (PA-NEDSS). All practitioners and facilities are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients seen at a location, the number of reportable diseases diagnosed at each location, and the type of individual hired to

perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by the proposed addition of § 27.33a, which will require reporting treatment provided to all suspected or confirmed cases of tuberculosis and certain sexually transmitted diseases. Practitioners and facilities will be required to report to the Department's already-existing electronic disease surveillance system or to the local health department. Practitioners and facilities that electronically report will need to implement a one-time change to their automated reporting system. Practitioners and facilities that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of practitioners and facilities that electronically and manually report. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Some health care practitioners and health care facilities, and individuals authorized by law to administer immunizations, will be financially impacted by the proposed addition of § 27.36 (relating to reporting immunization delivery), which will require these practitioners, facilities and individuals to report each immunization administration in all counties of this Commonwealth, except Philadelphia County, to the Department's designated immunization information system. Philadelphia County is excluded from this requirement as they have their own reporting system already in place. The Department estimates that approximately 21,000 health care practitioners, facilities and individuals will need to comply with this new

requirement. Out of this number, 16,250 are already voluntarily reporting to the Department's immunization electronic registry system (PIERS). The 4,750 not currently reporting will need to establish a process for reporting to PIERS, either electronically or manually, which may require additional staff or IT support and will vary depending on factors such as the number of immunizations that are being reported and who is hired to perform this function. The Department does not currently have sufficient data to estimate the financial impact to these 4,750 practitioners, facilities and individuals. For this reason, the Department is estimating no overall financial impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by the proposed addition of § 27.37 (relating to reporting birth defects and congenital anomalies) which will require practitioners and facilities to report certain birth defects and congenital anomalies to the Department. Specifically, practitioners and facilities will need to establish a system for reporting birth defects to the Department's newly created electronic birth defects registry. This may involve creating an electronic system for automated reporting or allocating staff to manually submit data to the Department's birth defects registry, the cost of which will vary depending on factors such as the number of patients with reportable birth defects and the type of individual hired to perform this function. The Department does not have sufficient data to estimate the cost of creating an electronic system or the amount of staff time needed for such reporting. For this reason, the Department is estimating no overall fiscal impact for this requirement.

All health care practitioners and health care facilities will be financially impacted by new proposed § 27.71a, which will update the exclusion and readmission requirements for health care practitioners. The Department does not propose to increase the total number of entries which require exclusion; however, the proposed amendments do remove a broad symptom of disease

from the exclusion requirements and replace it with a specific disease. Health care practitioners may experience fewer exclusions because of this change, potentially resulting in savings in decreased time away from work. Health care facilities may lose less staff time to exclusions under this new proposed section, potentially resulting in savings. The Department cannot accurately estimate the savings of this proposed change due to the unpredictability of the number of symptomatic exclusions compared to illnesses for individual food handlers or each entity employing food handlers.

Health care practitioners within the scope of their practice who attend, treat or examine pregnant individuals may be financially impacted by the proposed addition of §§ 27.99a and 27.99b (relating to prenatal examination for hepatitis C and prenatal examination for HIV), which will require them to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. The factors in determining fiscal impact will vary depending on each practitioner's practice, such as additional paperwork to order the blood draw, additional time from staff drawing blood or costs in submitting the sample to a laboratory for testing. Costs for drawing the blood sample may be offset, in some cases, by the pregnant individual's insurance plan or the pregnant individual paying out-of-pocket for the test. Administrative costs, such as paperwork, may be absorbed by the practitioner as a cost of business. Due to these varying factors, the Department is not able to estimate a specific cost or savings impact. The Department is therefore estimating no overall cost as a result of this requirement.

Laboratories

All 9,589 clinical laboratories in this Commonwealth will be impacted by the proposed amendments. These laboratories will benefit from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for reportable

diseases, infections and conditions in proposed § 27.22, which will make it easier for them to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All clinical laboratories will be financially impacted by proposed amendments to § 27.22(b) and (c), which will increase the number of diseases, infections and conditions, as well as the types of data, that they will have to report to the Department. All clinical laboratories are already required to have a reporting system in place, and many already voluntarily report the diseases, infections and conditions proposed to be added. Most reporting is currently automated, and those that do not already report the additional diseases, infections and conditions will need to implement a one-time change to their automated reporting system. Clinical laboratories that manually report will need to allocate additional resources, including staff time, to submit data to the Department. The Department does not have sufficient data to determine the number of clinical laboratories that electronically and manually report to estimate the financial impact to these practitioners and facilities. In addition, for those that manually report, fiscal impact will vary based on factors such as the number of patients being treated at each location and the type of individual hired to perform this function. For these reasons, the Department is estimating no overall fiscal impact for this requirement.

Clinical, research or commercial laboratories, in this Commonwealth, that are registered with the Federal Select Agent Program (FSAP) to possess, use or transfer select agents or toxins will be impacted by the addition of proposed § 27.22a (relating to reporting of select agents or toxins), which will require these laboratories to report a detected release, exposure, loss or theft

of a select agent or toxin to the Department's Bureau of Laboratories. Currently, there are six laboratories to whom this requirement will apply. These laboratories will need to add the Department to any existing process or system they currently have in place for complying with already-existing requirements by FSAP. The Department does not have sufficient data to estimate the cost of this task but anticipates that any cost would be minimal. For this reason, the Department is estimating no overall fiscal impact for this requirement.

Schools, Colleges, Universities and Child Care Group Settings

All 500 school districts, which range in size from approximately 200 students to more than 140,000 students, and more than 160 brick-and-mortar charter schools and 14 cyber charter schools, which educate approximately 135,000 students, and the approximately 199,000 individuals employed by public and private schools, will be impacted by the proposed amendments. Approximately 400 colleges and universities in this Commonwealth, and 633,991 students and 161,146 employees in those settings, will be impacted by the proposed amendments. Additionally, all 6,378 child care group settings in this Commonwealth, and 96,197 individuals employed in those settings, will be impacted by the proposed amendments. Schools, colleges, universities and child care group settings will be positively impacted from proposed amendments to reflect current terminology and to enhance readability, such as the proposed alphabetical chart for exclusion and readmission requirements in proposed § 27.71a, which will make it easier to comply with the regulations, which may result in cost savings to practitioners and facilities through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

All schools, colleges, universities and child care group settings may be financially impacted by proposed amendments to § 27.71a, which will add exclusion and readmission requirements for 18 diseases, infections and conditions to the existing list. The proposed amendments, including the addition of exclusion and readmission requirements for 18 new diseases, infections and conditions, align with current recommendations from the American Academy of Pediatrics (AAP) and will ensure the health and safety of students and staff attending these entities. However, these entities may also be financially impacted by an increase in staff and student absences from this expansion, necessitating the need, for example, substitute teachers. Because this cost will vary based on the number of illnesses and time missed, the Department is not able to estimate a specific cost. For that reason, the Department is estimating no overall fiscal impact for this requirement.

All schools may be impacted by the proposed addition of § 27.60c, which will require a school to provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises or attending a school function. Compliance with this requirement may result in a time disruption to schools, which will vary based on the disease, infection of condition being investigated. Because of the inability to estimate a specific cost, the Department is estimating no overall fiscal impact for this requirement.

Veterinarians

Approximately 3,200 veterinarians in this Commonwealth will be impacted by the proposed amendments. All veterinarians will be positively impacted by the proposed addition of specific diseases, infections and conditions in § 27.24a (relating to reporting of cases by

veterinarians). The Department consulted with the Pennsylvania Department of Agriculture, and is proposing to limit the reporting of diseases, infections and conditions, which may be transmitted from animals to humans, to the Department that are already not being reported to the Department of Agriculture to prevent double reporting. This may result in a cost savings through efficiencies. Factors that would determine the cost savings through administrative efficiencies are variable and dependent on many factors. For that reason, the Department is estimating no fiscal savings for the regulated community due to these proposed amendments.

General Public

The general public, consisting of approximately 13 million individuals in this Commonwealth, will be impacted by the proposed amendments. The public will be positively impacted by proposed amendments to expand various reporting requirements by health care practitioners, health care facilities and laboratories, as this information will be utilized by the Department to conduct investigations and take appropriate measures to protect public health. Other proposed amendments clarifying existing requirements, such as the disease control measures that the Department may take under § 27.60 (relating to disease control measures), will also protect the public health by ensuring that the Department may act appropriately and quickly when needed, which will result in benefits such as preventing the spread of a disease, condition or illness. This could result in cost savings to the public, such as a reduction in health care expenses and less missed time from work. Factors involved in calculating this cost savings will vary depending on the circumstances. For that reason, the Department is estimating no fiscal savings to the general public due to these amendments.

Additional proposed requirements relating to exclusion and readmission of students, children, staff, food handlers and health care practitioners may result in a financial impact due to

individuals missing time from work or school, but will prevent the spread of contagious diseases, infections and conditions in settings such as schools, colleges, universities, and child care group settings. However, the Department made an effort, where appropriate, to remove the need for health care provider verification for readmission, which will alleviate the time and monetary burden for parents, guardians, and other individuals potentially impacted by the proposed exclusion requirements. Factors involved in calculating cost and savings related to time vary depending on the circumstances. Therefore, the Department is estimating no overall fiscal impact for these requirements.

Pregnant individuals will be impacted by the proposed addition of §§ 27.99a and 27.99b, which will require health care practitioners acting within the scope of their practice who attend, treat or examine pregnant individuals to obtain and submit a sample of blood to be tested for hepatitis C and HIV, unless the individual objects. The estimated cost to pregnant individuals will vary depending on health insurance plans. For example, these individuals may need to pay a co-pay for an office visit as well as for the blood draw. Co-pays for an office visit typically average $25 for a primary care physician and $30 for an obstetrician. *See* Machlin, S. & Mitchell, E. (2018). Statistical Brief #517: Expenses for Office-Based Physician Visits by Specialty and Insurance Type, 2016. Retrieved from https://meps.ahrq.gov/data_files/publications/st517/stat517.shtml. The cost for the actual blood draw will vary as well, depending on insurance coverage, and the method utilized for the draw. Hepatitis C and HIV may be tested through one blood draw or the submission of separate blood draws for each condition. Quest Diagnostics, for example, charges approximately $62 for a single test for hepatitis C and $85 for HIV, and $282 for a combined blood draw that tests for both. *See* Quest Diagnostics. (2025). Hepatitis C Test with Confirmation. Retrieved from

https://www.questhealth.com/product/hepatitis-c-test-with-confirmation-8472M.html; Quest Diagnostics Inc. (2025). HIV 1 & 2 Test with Confirmation. Retrieved from https://www.questhealth.com/product/hiv-1-2-test-with-confirmation-91431M.html; and Quest Diagnostics Inc. (2025). STD Screening Test Panel – Expanded. Retrieved from https://www.questhealth.com/product/std-screening-panel-expanded-37328M.html. On the other hand, the estimated lifetime cost of treatment for hepatitis C ranges from $26,400 to $84,000 and for HIV ranges from $420,285 to over $1 million. *See* University of Pennsylvania. (2018). Cost-effective Screening and Treatment of Hepatitis C. Retrieved from https://ldi.upenn.edu/our-work/research-updates/cost-effective-screening-and-treatment-of-hepatitis-c/; Henry, B. (2018). "Drug Pricing & Challenges to Hepatitis C Treatment Access." *J. Health Biomed Law* 14, 265-83; and Bingham, A., et al. (2021). "Estimated Lifetime HIV-Related Medical Costs in the United States." *Sex. Transmitted Dis.* 48(4), 299-304. However, these additional tests will positively impact these individuals and their unborn fetuses by ensuring early, preventative treatment is provided to improve the health outcome of both the pregnant individual and the child, which may result in a cost savings to these individuals and their children. Because a specific cost and savings estimate will vary depending on the number of pregnant individuals being tested, as well as their specific insurance plans, the Department is estimating no fiscal cost of savings to these individuals.

Local governments

The Department does not anticipate any specific costs or savings to local governments. All 11 local health departments will be impacted by proposed amendments to §§ 27.32d and 27.32e, which will allow local health authorities to have access to, review and conduct audits of HIV-related patient records. This proposed amendment will allow for local health department

disease investigation personnel to conduct all disease investigations within their jurisdiction, where they are the primary investigator, potentially minimally increasing the workload for those personnel. Local health departments will be impacted by proposed amendments to § 27.42a, which will extend the deadline to submit a case investigation report from each case investigation that results in a confirmed reportable disease. The proposed 2-day extension will give local health departments more time to complete reports. Local health departments will be impacted by proposed amendments to § 27.67 (relating to movement of persons and animals subject to isolation or quarantine by action of a local health authority or the department), which will require local health departments to grant permission for the interstate transportation of a person or animal under isolation or quarantine if involved. This proposed amendment will ensure that local health departments are informed and involved in such cases of interstate transportation.

Department

The Department will incur costs as a result proposed amendments to § 27.22(l), which will require a clinical laboratory, if it suspects the presence of certain select agents or toxins, to submit specimens or cultures to BOL or another laboratory designated by BOL. There is no additional cost to the laboratory, but there would be a cost to BOL, who bears all of the associated costs for courier pick-up and transport of the suspected specimens, and for the testing, and for shipping presumptive positive specimens to the CDC for confirmatory testing. The Department is not able to estimate a specific cost, as this would depend on the number of specimens or cultures sent to BOL. However, courier costs vary by county location, currently ranging from $50 to $90 plus a fuel surcharge. BOL estimates an average cost of $75/specimen, which is typically delivered next day. During emergent events (*e.g.* H5 avian influenza), BOL

requests express delivery (same day pickup and drop-off at $2.25/mile). In that scenario, a package from Erie County would cost over $900, for example.

The Department will incur costs as a result of new proposed § 27.37, which will require the Department to create a birth defects registry for the reporting of certain birth defects and congenital anomalies. To estimate the cost of this new proposed requirement, the Department consulted with other states, including New Jersey, Ohio and Florida. The Department determined through these and other internal discussions that the cost will vary depending on whether the Department chooses to add a module to its already existing newborn screening system or to build a new system. The Department estimates that the cost to add a module to its already existing newborn screening system would result in a one-time cost of $150,000 plus an estimated $30,000 annually thereafter to cover system maintenance and an estimated $40,000 to $100,000 for hosting data depending on what data is collected and stored. The estimated startup and maintenance cost, not including staff, is less than New Jersey, who indicated they budget for $250,000 to $280,000 annually for operation of their modification and maintenance of their birth registry system.

Once the birth defects registry is established, the Department will need to hire staff to manage it. The Department estimates a total of $1,523,977 for staff for the first year of operation. This estimate includes an estimated $1,512,877 for salaries and benefits and initial operating costs of $11,100. The breakdown includes two IT contractors for project management and internal support at an estimated cost of $220,000 per contractor's salary, one full-time public health program administrator with an estimated starting salary of $66,000 to $100,000, who will be tasked with creating protocols and documents, one full-time epidemiologist and one full-time epidemiology research associate for support and investigative work, conducting data analytics,

and curating reports from the data collected. The Department estimates the starting salary for these two individuals to be $112,000 to $170,000 each. Lastly, the total costs include one part-time administrative person, for support, at a salary of $44,000 to $67,000, dependent upon experience. The Department also estimates that it will incur a cost for education and training of staff in the use of the birth defects registry. The Department estimates this cost to be approximately $20,000 to $30,000 at least for the first two years and then can be scaled back over time.

The Department anticipates applying for a CDC grant to offset the initial start-up and ongoing costs of the birth defects registry. This amount varies. Although it is not guaranteed, based on conversations with other states, the Department believes that it could receive between $300,000 to $600,000 from this grant, assuming that the grant is approved and funds are available. The Department proposes delaying the effective date of proposed § 27.37 to accommodate the development and full implementation of the birth defects registry. Section 27.37 will become effective 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry.

Paperwork Requirements

The Department anticipates that the following requirements will result in either a one-time update to health care practitioners, health care facilities and clinical laboratories' internal automated reporting systems linked to PA-NEDSS, or the allocation of additional staff time to manually enter data for PA-NEDSS:

- Proposed § 27.21a requires health care practitioners and health care facilities to report an additional 73 diseases, infections and conditions to the Department.

- Proposed § 27.22 requires clinical laboratories to report the presence of an additional 53 diseases, infections and conditions to the Department.

Additionally, the proposed amendments to § 27.24a will require veterinarians to report an additional four diseases, infections and conditions found in animals to the Department. The Department has made efforts to minimize double reporting by only adding a few specific diseases, infections and conditions that are not currently reported to the Pennsylvania Department of Agriculture.

New proposed § 27.22a will require clinical, research or commercial laboratories that possess, use or transfer select agents or toxins to report release, exposure, loss or theft of such to the Department. The Department has modeled its required data elements after the FSAP requirements so that a laboratory experiencing such an event can send the same report to FSAP and the Department and comply with this proposed amendment. New proposed § 27.4a will require hospitals to report emergency department visit data to the Department. All hospitals are already voluntarily reporting this data to the Department. New proposed § 27.33a will require health care practitioners and health care facilities to report treatment of six sexually transmitted diseases as well as tuberculosis to the Department. New proposed § 27.33a will require health care practitioners and health care facilities to report animal bites, scratches or contamination of open wounds or mucous membranes to the Department.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 4, 2026, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the

Chairpersons of the Senate Health and Human Services Committee and the House Health Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations, or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for the review of comments, recommendations or objections that are raised prior to final publication of this rulemaking by the Department, the General Assembly, and the Governor.

ANNEX A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

Subchapter A. GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

[*ACIP*—The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, United States Department of Health and Human Services.]

AIDS ***[(Acquired Immune Deficiency Syndrome)*—As defined by the CDC case definition published in the CDC *Morbidity and Mortality Weekly Report* (MMWR). (The Department will publish in the *Pennsylvania Bulletin* a reference to a CDC update of the case definition within 30 days of its publication in the MMWR)]** **—*Acquired Immune Deficiency Syndrome*—A late-stage HIV infection where the number of an individual's CD4 cells falls below 200 cells per cubic millimeter of blood, or an individual develops one or more opportunistic infections regardless of CD4 count.**

Act—The Disease Prevention and Control Law of 1955 (35 P. S. §§ 521.1—521.21).

***Animal*—Any organism, other than a human, including mammals, reptiles, amphibians, insects, birds or fish, believed to be capable of carrying or harboring an infectious agent and transmitting it to other animals or humans.**

Anonymous HIV Testing—HIV testing performed at a State-designated HIV testing site for an individual who chooses not to provide **[his]** **their** name in giving consent for the testing.

***Assisted living residence*—As defined in the Human Services Code (62 P.S. § 1001) (definition of "assisted living residence").**

***Birth Defects Registry*—The electronic platform the Department uses to collect and manage information reportable under § 27.37 (relating to reporting of birth defects and congenital anomalies).**

Board—The Advisory Health Board of the Department.

***Brain-related tumor*—As defined in 42 U.S.C. § 280e(a)(2)(B) (relating to national program of cancer registries).**

CDC—**The United States** Centers for Disease Control and Prevention.

Caregiver—The entity or individual responsible for the safe and healthful care or education of a child in a child care group setting.

Carrier—A person who, without any apparent symptoms of a communicable disease, harbors a specific infectious agent and may serve as a source of infection.

Case—A person or animal that is determined to have or suspected of having a disease, infection or condition.

[*Case report form*—The form designated by the Department for reporting a case or a carrier.]

[*Central office*—Department headquarters located in Harrisburg.]

Child—A person under 18 years of age.

Child care group setting—The premises in which care **in lieu of care by the parent or guardian for part of a 24-hour day** is provided at any one time to four or more children,

unrelated to the operator.

Clinical laboratory—A laboratory for which a permit has been issued to operate as a clinical laboratory under the Clinical Laboratory Act (35 P. S. §§ 2151—2165).

***Close contact*—A person who has been in close proximity to a person with a disease, infection or condition of public health significance for a sufficient time and in a manner to have possibly been infected with that disease or condition.**

***Commercial laboratory*—A laboratory that is free-standing and not associated with a hospital or other health care organization.**

Communicable disease—An illness which is capable of being spread to a susceptible host through the direct or indirect transmission of an infectious agent or its toxic product by an infected person, animal or arthropod, or through the inanimate environment.

Communicable period—The time during which an etiologic agent may be transferred directly or indirectly from an infected person to another person, or from an infected animal to a person.

***Condition*—Noninfectious medical ailment or other health-related event.**

Confidential HIV testing—HIV testing performed for an individual who, in giving **[his]** consent for the testing, provides **[his] their** name and other personal or demographic identifiers.

Contact—A person or animal known to have had an association with an infected person or animal which presented an opportunity for acquiring the infection.

[*County morbidity reporting area*—A county so designated by the Board wherein initial reports for communicable and noncommunicable diseases are to be reported to the State health center of the Department.]

***Culture-independent diagnostic test*—A laboratory test that detects the presence of an antigen or nucleic acid associated with a specific pathogen, without growing the pathogen in a laboratory.**

***DHHS*—The United States Department of Health and Human Services.**

***DOT—directly observed therapy*—The direct observance by a trained health care worker of a tuberculosis patient's ingestion of an oral medication or the administration of a tuberculosis patient's injectable medication.**

Department—The Department of Health of the Commonwealth.

District office—One of the district headquarters of the Department located within this Commonwealth.

Electronic Disease Surveillance System—Any of the electronic, web-based platforms that the Department uses to collect and manage information reportable under § 27.2 (relating to specific identified reportable diseases, infections and conditions). For purposes of this chapter, the term includes an electronic laboratory reporting system.

Electronic Laboratory Reporting System—The electronic platform that the Department uses to receive and process information electronically generated by clinical laboratories to fulfill their reporting responsibilities under § 27.22 (relating to reporting of cases by clinical laboratories). Information submitted to the electronic laboratory reporting system will be routed to the Department's electronic disease surveillance system when appropriate.

***Emerging disease or condition*—A disease or condition that has been identified in a population for the first time, or that may have existed previously but is rapidly increasing in incidence in a geographic area or subset of the population. Such disease or condition may be caused by any of the following:**

(i) A previously undetected or unknown infectious agent.

(ii) A known agent that has spread to a new geographic location or population.

(iii) A previously known agent whose role in specific diseases has previously gone unrecognized.

(iv) A reemergence of an agent whose incidence of disease had significantly declined in the past but whose incidence of disease has reappeared. This class of diseases is known as reemerging infectious diseases.

(v) An infectious agent with antibiotic resistance patterns of public health significance or a disease with novel mechanisms of resistance, such as an XDR or MDR disease.

(vi) Use of or exposure to a product or substance that causes unexpected illness or a health-related event.

FDA—**The United States** Food and Drug Administration.

***Food*—A raw, cooked or processed edible substance, ice, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.**

***Food handler*—An individual who, as part of their occupation or volunteer work, may have direct contact with food or a food-contact surface. This term includes, but is not limited to, restaurant workers and servers, grocery store workers, those volunteering at food service places or events, and those working at food manufacturing facilities.**

***Food-contact surface*—A surface that has direct contact with food ordinarily during the normal course of operations. This term includes utensils and surfaces of equipment which come into direct contact with food.**

***HIV—Human Immunodeficiency Virus*—A virus that attacks cells that help the body**

fight infection, making a person more vulnerable to other infections and diseases and if left untreated can lead to AIDS.

HIV services—The range of services, including prevention, counseling, testing, treatment, case management, support and referral services, which are provided to persons infected with or affected by HIV or AIDS, and are intended to alleviate physical and psychosocial problems created by these diseases and conditions.

Health care facility—

(i) A **[chronic disease, or other type of]** hospital, a home health care agency, a hospice, a long-term care nursing facility, **an assisted living residence, a personal care home,** a cancer treatment center using radiation therapy on an ambulatory basis, an ambulatory surgical facility, a birth center, and an inpatient drug and alcohol treatment facility, regardless of whether the health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government.

(ii) The term does not include:

(A) An office used primarily for the private practice of a health care practitioner.

(B) A facility providing treatment solely on the basis of prayer or spiritual means in accordance with the tenets of any church or religious denomination.

(C) A facility conducted by a religious organization for the purpose of providing health care services exclusively to clergy or other persons in a religious profession who are members of a religious denomination.

Health care practitioner—An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.

Health care provider—An individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), the Commonwealth, or a political subdivision, or instrumentality (including a municipal corporation or authority) thereof, that operates a health care facility.

***Hospital*—As defined in chapter 8 of the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b).**

Household contact—A person living in the same residence as a case, including a spouse, child, parent, relation or other person, whether or not related to the case.

***Immunization information system*—The electronic platform that the Department uses to collect immunization records under § 27.36 (relating to reporting immunization delivery).**

Infectious agent—Any organism **or agent**, such as a virus, bacterium, fungus **[or]** parasite **or prion**, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease.

Isolation—The separation for the communicable period of an infected person or animal from other persons or animals, in such a manner as to prevent the direct or indirect transmission of the infectious agent from infected persons or animals to other persons or animals who are susceptible or who may spread the disease to others.

[*LMRO—Local morbidity reporting office*—A district office of the Department or a local health department.]

Local health authority—A county or municipal department of health, or board of health of a municipality that does not have a department of health. The term includes a sanitary board.

Local health department—Each county department of health under the Local Health Administration Law (16 P. S. § § 12001—12028), and each department of health in a

municipality approved for a Commonwealth grant to provide local health services under section 25 of the Local Health Administration Law (16 P. S. § 12025).

Local health officer—The person appointed by a local health authority to head the daily administration of duties imposed upon or permitted of local health authorities by State laws and regulations.

***MDR—multidrug-resistant*—Lack of susceptibility to at least one agent in three or more chemical classes of antibiotic (*e.g.*, a beta-lactam, an aminoglycoside or a macrolide).**

***Mammal*—A vertebrate animal of the class *Mammalia*, other than a human, which shares at least three characteristics not found in other animals: three middle ear bones, hair, and the production of milk by modified sweat glands.**

Medical record—An account compiled by **[physicians and other health professionals including] a health care practitioner that includes** a patient's medical history; present illness; findings on physical examination; details of treatment; reports of diagnostic tests; findings and conclusions from special examinations; findings and diagnoses of consultants; diagnoses of the responsible **[physician] health care practitioner**; notes on treatment, including medication, surgical operations, radiation, and physical therapy; and progress notes by **[physicians, nurses and other health professionals] health care practitioners**.

Modified quarantine—A selected, partial limitation of freedom of movement determined on the basis of differences in susceptibility or danger of disease transmission which is designated to meet particular situations. The term includes the exclusion of children from school and the prohibition, or the restriction, of those exposed to a communicable disease from engaging in particular activities.

Monitoring of contacts—The close supervision of persons and animals exposed to a

communicable disease without restricting their movement.

Municipality—A city, borough, incorporated town or township.

***Normally sterile body site*—Includes blood, cerebrospinal fluid, pleural fluid, peritoneal fluid, pericardial fluid, joint/synovial fluid, bone, muscle, or an internal body site, such as a lymph node or the brain.**

***Of public health significance*—A disease, infection or condition that can reasonably be expected to lead to adverse health effects in the community.**

Operator—The legal entity that operates a child care group setting or a person designated by the legal entity to serve as the primary staff person at a child care group setting.

Outbreak—An unusual increase in the number of cases of a disease, infection or condition, whether reportable or not as a single case, above the number of cases that a person required to report would expect to see in a particular geographic area or among a subset of persons (defined by a specific demographic or other features).

***Pandrug-resistant*—Non-susceptibility to all agents in all antimicrobial categories (*i.e.*, bacterial isolates are not susceptible to a clinically available drug).**

***Partner services*—A broad array of services offered to persons with HIV, sexually transmitted infections or other potentially sexually transmitted diseases, and their partners. The term includes partner elicitation and notification, treatment or linkage to HIV medical care, prevention counseling, testing of partners for HIV or sexually transmitted infections, pre-exposure prophylaxis (PrEP), hepatitis screening and vaccination, and linkage or referral to other services, such as reproductive health services, prenatal care, substance use treatment, social support, housing assistance, legal services and mental health services.**

Perinatal exposure of a newborn to HIV—The potential perinatal transmission of HIV to a newborn indicated by a positive HIV test result for [**the pregnant woman or mother of a newborn]** **a pregnant or postpartum individual**.

***Personal care home*—As defined in the Human Services Code (62 P.S. § 1001) (definition of "personal care home").**

***Pesticide-related illness or injury*—An acute adverse effect resulting from exposure to a pesticide, as defined under section 136(u) of the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C.A. § 136(u)), including health effects due to an unpleasant odor, injury from explosion of a product, inhalation of smoke from a burning product and allergic reaction.**

[*Physician*—An individual licensed to practice medicine or osteopathic medicine within this Commonwealth.]

Placarding—The posting on a home or other building of a sign or notice warning of the presence of communicable disease within the structure and the danger of infection therefrom.

***Public health emergency*—An event that affects or has the potential to seriously affect the health, safety or welfare of a significant number of persons of this Commonwealth, and whose scale, timing or unpredictability threatens to overwhelm routine medical or public health capabilities. The term includes any event that has been declared to be a public health emergency by the Governor of this Commonwealth or by the Secretary of DHHS.**

Quarantine—

(i) The limitation of freedom of movement of a person or an animal that has been exposed to a communicable disease, for a period of time equal to the longest usual incubation period of the disease, or until judged noninfectious by a **[physician]** **health care practitioner acting**

within their scope of practice, in a manner designed to prevent the direct or indirect transmission of the infectious agent from the infected person or animal to other persons or animals.

(ii) The term does not exclude the movement of a person or animal from one location to another when approved by the Department or a local health authority under § 27.67 (relating to the movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department).

*Reportable disease, infection**[,]** or condition*—A disease, infection**[,]** or condition, made reportable by **[§ 27.2 (relating to specific identified reportable diseases, infections and conditions)]** **Subchapter B (relating to the reporting of diseases, infections and conditions)**.

***Research laboratory*—A laboratory operated solely for research and teaching, and conducting analyses, the results of which are not used for clinical application.**

SHC—State Health Center—The official headquarters of the Department in a county, other than a district office.

***School*—An institution for learning as follows:**

(i) A "school entity" or "charter school entity" as defined in section 17-1703-A of the Public School Code of 1949 (24 P.S. § 17-1703-A).

(ii) A licensed private academic school. This includes any school licensed and regulated by the State Board of Private Academic Schools pursuant to the Private Academic Schools Act (24 P.S. §§ 6701—6721) and its regulations.

(iii) A nonpublic school. This includes any school required to comply with t 24 P.S. § 13-1327(b) and (c) despite not being public and not required to be licensed. This includes any school operated by a bona fide church or other religious body.

Secretary—The Secretary of the Department.

Segregation—The separation for special control or observation of one or more persons or animals from other persons or animals to facilitate the control of a communicable disease.

***Select agent or toxin*—Biological material that has the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products, as determined by the DHHS and the USDA under 7 CFR 331.3 (relating to PPQ select agents and toxins), 9 CFR 121.3 (relating to VS select agents and toxins), 9 CFR 121.4 (relating to overlap select agents and toxins) and 42 CFR 73.3 (relating to HHS select agents and toxins).**

Sexually transmitted disease—A disease which, except when transmitted perinatally, is transmitted almost exclusively through sexual contact.

State-designated anonymous HIV testing site—An HIV testing site supported by the Department either through direct funding or payment for testing, which provides anonymous and confidential testing and which agrees to adhere to the CDC's counseling and testing standards and guidelines issued by the Department.

***Student*—A person attending a school, college or university.**

***Surveillance*—The ongoing, systematic collection, analysis and interpretation of health-related data essential to planning, implementing and evaluation of public health practice.**

[*Surveillance of disease*—The continuing scrutiny of all aspects of occurrence and spread of disease that are pertinent to effective control.]

***Syndromic surveillance*—Surveillance of diseases, symptoms and conditions conducted using near real-time data collected for other purposes, such as electronic medical records, poison control center data and other sources.**

***Syndromic Surveillance System*—The electronic platform the Department uses to receive and process information reportable under § 27.4a (relating to reporting hospital emergency department visit data for syndromic surveillance).**

***Unusual occurrence*—A pattern or manifestation of a disease or condition that is unexpected or unprecedented. This could include an uncommon disease or condition, a common disease or condition in an uncommon segment of the population, a disease or condition presenting with atypical signs and symptoms or mode of transmission, or a disease or condition displaying an unusual pattern of antimicrobial resistance.**

***USDA*—The United States Department of Agriculture.**

Volunteer—A person who provides services to a school or child care group setting without receiving remuneration.

***XDR—extensively drug-resistant*—Non-susceptibility to at least one agent in all but one or two antimicrobial categories (*i.e.*, bacterial isolates remain susceptible to drugs from at most two classes of antibiotic).**

§ 27.2. Specific identified reportable diseases, infections and conditions.

The diseases, infections and conditions in Subchapter B (relating to the reporting of diseases, infections and conditions) are reportable to the Department or the appropriate local health authority by the persons or entities in the manner and within the time frames set out in this chapter.

§ 27.3. Reporting outbreaks, [and] unusual diseases, infections and conditions, public health emergencies.

(a) ***Outbreaks.*** **[A] Unless otherwise directed by the Department, a** person required to report under this chapter shall report an outbreak **[within 24 hours, and in accordance with § 27.4 (relating to reporting cases)] to the Department as follows:**

(1) Immediately, by telephone, if the disease, infection or condition is one that requires immediate reporting under §§ 27.21a (relating to reporting of cases by health care practitioners and health care facilities) or 27.22 (relating to reporting of cases by clinical laboratories).

(2) Otherwise, by telephone, within 24 hours.

(b) ***Unusual diseases, infections and conditions.*** **[A] Unless otherwise directed by the Department, a** person required to report under this chapter who suspects a public health emergency, shall report an unusual occurrence of a disease, infection or condition not listed as reportable in Subchapter B (relating to reporting of diseases, infections and conditions) or defined as an outbreak**[, within 24 hours, and in accordance with § 27.4] within 30 minutes, by telephone to the Department**.

(c) ***Public health emergencies.*** **[Any] Unless otherwise directed by the Department, an** unusual or group expression of illness which the Department designates as a public health emergency shall be reported **[within 24 hours, and in accordance with § 27.4] within 30 minutes, by telephone to the Department**.

§ 27.4. Reporting cases.

(a) Except where otherwise noted in this chapter, a case shall be reported to the Department through the appropriate electronic disease surveillance system.

(b) A reporter may make a preliminary report of a case by telephone. The preliminary report must be followed by a formal report made through the appropriate electronic disease surveillance system.

(c) A case shall be reported using the appropriate case report format. The requested information shall be provided by the reporter, irrespective of the manner in which the report is submitted. Access to the appropriate electronic disease surveillance system may be obtained from the Department upon request.

§ 27.4a. Reporting hospital emergency department visit data for syndromic surveillance.

(a) A hospital shall report emergency department visit data to the Department's syndromic surveillance system.

(b) The hospital shall include the following data elements in the report submitted under subsection (a):

(1) The name of the facility or facility identifier.

(2) Date and time of patient visit.

(3) Patient age in years or date of birth.

(4) Patient gender.

(5) Patient race.

(6) Patient ethnicity.

(7) Chief complaint or reason for visit.

(8) Patient or visit identifier.

(9) Patient's home zip code.

(10) Diagnosis codes.

(11) Diagnosis description.

(12) Disposition of visit.

(13) Patient death, if applicable.

(14) Other data elements deemed necessary by the Department.

(c) The hospital shall make the report, required under subsection (a), in as near to real-time as possible, but no later than 24 hours after presentation of the patient at the emergency department.

(d) A hospital shall respond to Department inquiries regarding the data submitted under this section within 24 hours.

§ 27.4b. Additional reports.

Persons or entities required to report under this chapter shall provide any additional reports deemed necessary to prevent and control the spread of disease, upon request of the Department.

§ 27.5a. Confidentiality of [case] reports.

[Case reports submitted to the Department or to an LMRO] Except as provided for in section 15.1 of the act (35 P.S. § 521.15a) and below, reports submitted under this chapter are confidential. Neither the reports, nor any information contained in them which identifies or is perceived by the Department or the **[LMRO] local health department** as capable of being used to identify a person named in a report, will be disclosed to any person who is not an authorized **[employe] employee** or agent of the Department or the **[LMRO] local health department**, and who has a legitimate purpose to access case information, except for any of the following reasons:

(1) When disclosure is necessary to carry out a purpose of the act, as determined by the Department or **[LMRO] local health department**, and disclosure would not violate another act or regulation.

(1.1) When disclosure is necessary to inform the public of the risk of a communicable disease, as determined by the Department or local health department, and disclosure would not violate another act or regulation.

(2) When disclosure is made for a research purpose for which access to the information has been granted by the Department or **[an LMRO]** **local health department**. Access shall be granted only when disclosure would not violate another act or regulation. The research shall be subject to strict supervision by the **[LMRO]** **Department or local health department** to ensure that the use of information disclosed is limited to the specific research purpose and will not involve the further disclosure of information which identifies or is perceived as being able to be used to identify a person named in a report.

* * * * *

Subchapter B. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS

GENERAL

§ 27.21a. Reporting of cases by health care practitioners and health care facilities.

(a) **[Except as set forth in this section or as otherwise set forth in this chapter, a health care practitioner or health care facility is required to report a case of a disease, infection or condition in subsection (b) as specified in § 27.4 (relating to reporting cases), if the health care practitioner or health care facility treats or examines a person who is suffering from or who the health care practitioner or health care facility suspects, because of symptoms or the appearance of the individual, of having a reportable disease, infection or condition]** **A health care practitioner or health care facility shall report a case of a disease, infection or condition listed in subsection (b), if the practitioner or facility diagnoses, treats or suspects**

because of symptoms or appearance, a person of having that reportable disease, infection or condition, except:

(1) **[A] Where a** health care practitioner or health care facility [**is not required to report a case if that health care practitioner or health care facility]** has reported the case previously.

(1.1) As otherwise directed in this chapter or by the Department.

(2) **[A health care practitioner or health care facility is not required to report a case of influenza unless the disease is confirmed by laboratory evidence.]** **{Reserved}.**

(3) **[A health care practitioner or health care facility is not required to report a case of chlamydia trachomatis infection unless the disease is confirmed by laboratory evidence of the infectious agent.]** **{Reserved}.**

(4) **[A health care practitioner or health care facility is not required to report a case of cancer unless the health care practitioner or health care facility provides screening, therapy or diagnostic services to cancer patients.]** **{Reserved}.**

(5) **[Only physicians and hospitals are required to report cases of AIDS.]** **{Reserved}.**

(b) **[The following diseases, infections and conditions in humans are reportable by health care practitioners and health care facilities within the specified time periods and as otherwise required by this chapter:**

(1) The following diseases, infections and conditions are reportable within 24 hours after being identified by symptoms, appearance or diagnosis:

Animal bite. Anthrax. Arboviruses. Botulism. Cholera. Diphtheria. Enterohemorrhagic E. coli. Food poisoning outbreak. Haemophilus influenzae invasive disease. Hantavirus pulmonary syndrome. Hemorrhagic fever. Lead poisoning. Legionellosis. Measles

(rubeola). Meningococcal invasive disease. Plague. Poliomyelitis. Rabies. Smallpox. Typhoid fever.

(2) The following diseases, infections and conditions are reportable within 5 work days after being identified by symptoms, appearance or diagnosis:

AIDS.

Amebiasis.

Brucellosis.

CD4 T-lymphocyte counts and percentages.

Campylobacteriosis.

Cancer.

Chancroid.

Chickenpox (varicella) (effective January 26, 2005).

Chlamydia trachomatis infections.

Congenital adrenal hyperplasia (CAH) in children under 5 years of age.

Creutzfeldt-Jakob Disease.

Cryptosporidiosis.

Encephalitis.

Galactosemia in children under 5 years of age.

Giardiasis.

Gonococcal infections.

Granuloma inguinale.

Guillain-Barre syndrome.

HIV (Human Immunodeficiency Virus).

HIV viral load test results, including detectable and undetectable viral load results, and all HIV genotyping results.

Hepatitis, viral, acute and chronic cases.

Histoplasmosis.

Influenza.

Leprosy (Hansen's disease).

Leptospirosis.

Listeriosis.

Lyme disease.

Lymphogranuloma venereum.

Malaria.

Maple syrup urine disease (MSUD) in children under 5 years of age.

Meningitis (All types not caused by invasive Haemophilus influenza or Neisseria meningitis).

Mumps.

Perinatal exposure of a newborn to HIV (effective October 18, 2002).

Pertussis (whooping cough).

Phenylketonuria (PKU) in children under 5 years of age.

Primary congenital hypothyroidism in children under 5 years of age.

Psittacosis (ornithosis).

Rickettsial diseases.

Rubella (German measles) and congenital rubella syndrome.

Salmonellosis.

Shigellosis.

Sickle cell disease in children under 5 years of age.

Staphylococcus aureus, Vancomycin-resistant (or intermediate) invasive disease.

Streptococcal invasive disease (group A).

Streptococcus pneumoniae, drug-resistant invasive disease.

Syphilis (all stages).

Tetanus.

Toxic shock syndrome.

Toxoplasmosis.

Trichinosis.

Tuberculosis, suspected or confirmed active disease (all sites).

Tularemia.] The following diseases, infections and conditions in humans shall be reported by health care practitioners and health care facilities to the Department in the time and manner specified, unless otherwise directed by this chapter or by the Department:

	Disease, Infection or Condition:	Manner of reporting to Department:	Timeframe for reporting after being identified by symptoms, appearance, laboratory result or diagnosis:
1.	Acute flaccid myelitis (AFM).	Electronic disease surveillance system.	Within 24 hours.
2.	Amebiasis.	Electronic disease surveillance system.	Within 5 work days.
3.	Anaplasmosis.	Electronic disease surveillance system.	Within 5 work days.

4.	**Anthrax.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours to the electronic disease surveillance system.**
5.	**Arboviral infection (*i.e.*, viral infection transmitted through the bite of an arthropod such as a mosquito or tick), not otherwise listed.**	**Electronic disease surveillance system.**	**Within 24 hours.**
6.	**Arenavirus infection (including infections with Junin, Machupo, Guanarito and Sabia viruses).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours to electronic disease surveillance system.**
7.	**Arsenic level greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine.**	**Electronic disease surveillance system.**	**Within 24 hours.**
8.	***Aspergillus fumigatus* infection, azole-resistant.**	**Electronic disease surveillance system.**	**Within 5 work days.**
9.	**Babesiosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
10.	***Bacillus cereus* Biovar *anthracis* infection.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
11.	***Bartonella* infection, including "cat scratch fever."**	**Electronic disease surveillance system.**	**Within 5 work days.**
12.	**Botulism, excluding infant botulism.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
13.	**Botulism, infant.**	**Electronic disease surveillance system.**	**Within 24 hours.**

14.	**Brucellosis.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
15.	***Burkolderia pseudomallei* (melioidosis) or *Burkolderia mallei* (glanders) infection.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
16.	**Cadmium level greater or equal to 5 micrograms per liter (µg/L) of whole blood, or 3 micrograms per gram (µg/g) of creatinine.**	**Electronic disease surveillance system.**	**No later than the next work day.**
17.	**Campylobacteriosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
18.	***Candida auris*.**	**Electronic disease surveillance system.**	**Within 24 hours.**
19.	**Carbapenemase-producing organisms, including carbapenem-resistant Enterobacterales, *Pseudomonas* species and *Acinetobacter* species.**	**Electronic disease surveillance system.**	**Within 24 hours.**
20.	**Carbon monoxide poisoning CO (carboxyhemoglobin) COHb greater or equal to 5% in blood.**	**Electronic disease surveillance system.**	**No later than the next work day.**
21.	**Chancroid.**	**Electronic disease surveillance system.**	**Within 5 work days.**
22.	**Chikungunya infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
23.	***Chlamydia trachomatis* infection.**	**Electronic disease surveillance system.**	**Within 5 work days.**
24.	**Cholera.**	**Electronic disease surveillance system.**	**Within 24 hours.**

25.	**Coccidioidomycosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
26.	**Coronavirus infection, novel, other than COVID-19, including Middle East Respiratory Syndrome (MERS) and the original Severe Acute Respiratory Syndrome (SARS).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
27.	**COVID-19 infection.**	**Electronic disease surveillance system.**	**Within 5 work days.**
28.	**Creutzfeldt-Jakob Disease.**	**Electronic disease surveillance system.**	**Within 5 work days.**
29.	**Cronobacter infection, infant.**	**Electronic disease surveillance system**	**Within 24 hours.**
30.	**Cryptosporidiosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
31.	**Cyclosporiasis.**	**Electronic disease surveillance system.**	**Within 24 hours.**
32.	**Dengue virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
33.	**Diphtheria.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
34.	**Eastern equine encephalitis virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
35.	**Ebola infection.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
36.	**Ehrlichiosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**

37.	**Emerging diseases or conditions.**	**Electronic disease surveillance system.**	**Within 24 hours.**
38.	**Encephalitis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
39.	**Filovirus infection, not otherwise listed.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
40.	**Foodborne illness due to toxins (including mushroom toxins, ciguatera toxins, scombrotoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, staphylococcus enterotoxin, *Bacillus cereus* toxin, and others).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
41.	**Free-living amoeba infection, including infections caused by *Acanthamoeba* spp., *Balamuthia mandrillaris*, and *Naegleria fowleri*.**	**Telephone and Electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
42.	**Gastrointestinal illness outbreak.**	**Telephone.**	**Within 24 hours.**
43.	**Giardiasis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
44.	**Gonococcal infection.**	**Electronic disease surveillance system.**	**Within 5 work days.**
45.	**Granuloma inguinale.**	**Electronic disease surveillance system.**	**Within 5 work days.**
46.	**Guillain-Barre syndrome.**	**Electronic disease surveillance system.**	**Within 5 work days.**
47.	***Haemophilus influenzae* invasive disease.**	**Electronic disease surveillance system.**	**Within 24 hours.**
48.	**Hantavirus pulmonary syndrome (HPS).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by**

			electronic disease surveillance system.
49.	**Harmful algal bloom related illness.**	**Electronic disease surveillance system.**	**No later than the next work day.**
50.	**Hemolytic uremic syndrome (HUS) with or without confirmation of *E. coli* infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
51.	**Hemorrhagic fever, viral, not otherwise listed.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
52.	**Hepatitis A, acute.**	**Electronic disease surveillance system.**	**Within 24 hours.**
53.	**Hepatitis B, acute.**	**Electronic disease surveillance system.**	**Within 24 hours.**
54.	**Hepatitis B, chronic.**	**Electronic disease surveillance system.**	**Within 5 work days.**
55.	**Hepatitis B, perinatal.**	**Electronic disease surveillance system.**	**Within 5 work days.**
56.	**Hepatitis C, acute.**	**Electronic disease surveillance system.**	**Within 5 work days.**
57.	**Hepatitis C, chronic.**	**Electronic disease surveillance system.**	**Within 5 work days.**
58.	**Hepatitis C, perinatal.**	**Electronic disease surveillance system.**	**Within 5 work days.**
59.	**Hepatitis D, acute.**	**Electronic disease surveillance system.**	**Within 5 work days.**
60.	**Hepatitis D, chronic.**	**Electronic disease surveillance system.**	**Within 5 work days.**
61.	**Hepatitis E, acute.**	**Electronic disease surveillance system.**	**Within 5 work days.**

62.	**Hepatitis E, chronic.**	**Electronic disease surveillance system.**	**Within 5 work days.**
63.	**Hepatitis, viral, other types.**	**Electronic disease surveillance system.**	**Within 5 work days.**
64.	**Histoplasmosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
65.	**Influenza (all types), confirmed by positive antigen or nucleic acid laboratory test, or point-of-care rapid test.**	**Electronic disease surveillance system.**	**Within 5 work days.**
66.	**Influenza-related deaths in children less than 18 years of age.**	**Electronic disease surveillance system.**	**Within 24 hours.**
67.	**La Crosse encephalitis virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
68.	**Lead results for persons of all ages, including negative results or results below the limit of detection, from venous or capillary blood specimens.**	**Electronic disease surveillance system.**	**Within 24 hours.**
69.	**Legionellosis, including Pontiac fever.**	**Electronic disease surveillance system.**	**Within 24 hours.**
70.	**Leprosy (Hansen's disease).**	**Electronic disease surveillance system.**	**Within 5 work days.**
71.	***Leptospirosis (Leptospira interrogans)*.**	**Electronic disease surveillance system**	**No later than the next work day.**
72.	**Listeriosis.**	**Electronic disease surveillance system.**	**Within 24 hours.**
73.	**Lymphogranuloma venereum.**	**Electronic disease surveillance system.**	**Within 5 work days.**
74.	**Malaria.**	**Electronic disease surveillance system.**	**Within 5 work days.**

75.	**Marburg infection.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
76.	**Measles (rubeola).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
77.	**Meningitis (all types not caused by invasive Haemophilus influenza or *Neisseria meningitis*).**	**Electronic disease surveillance system.**	**Within 5 work days.**
78.	**Mercury level greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine or greater or equal to 5 micrograms per gram (µg/g) in hair.**	**Electronic disease surveillance system.**	**No later than the next work day.**
79.	**Monkeypox (mpox) infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
80.	**Mumps.**	**Electronic disease surveillance system.**	**Within 5 work days.**
81.	***Neisseria meningitis* (meningococcus) invasive disease, including meningococcal meningitis.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
82.	**Nontuberculous mycobacteria, extrapulmonary infection.**	**Electronic disease surveillance system.**	**Within 5 work days.**
83.	**Novel influenza A virus infection (infection with an influenza A virus that is different from circulating human influenza H1 and H3 viruses).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**

84.	**Orthopox virus infection, not otherwise listed.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
85.	**Pandrug-resistant organism infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
86.	**Pertussis (whooping cough).**	**Electronic disease surveillance system.**	**Within 24 hours.**
87.	**Pesticide-related illness and injury, acute.**	**Electronic disease surveillance system.**	**No later than the next work day.**
88.	**Plague.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
89.	**Poliomyelitis.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
90.	**Poliovirus infection, nonparalytic.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
91.	**Powassan virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
92.	**Psittacosis (ornithosis).**	**Electronic disease surveillance system.**	**Within 5 work days.**
93.	**Q fever, acute and chronic.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**

94.	**Rabies, human.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
95.	**Ricin poisoning.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
96.	**Rickettsial disease, not otherwise listed, including rickettsialpox and typhus.**	**Electronic disease surveillance system.**	**Within 5 work days.**
97.	**Rubella (German measles) and congenital rubella syndrome.**	**Electronic disease surveillance system.**	**Within 24 hours.**
98.	**Salmonellosis.**	**Electronic disease surveillance system.**	**Within 24 hours.**
99.	**Shigellosis.**	**Electronic disease surveillance system.**	**Within 24 hours.**
100.	**Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC) infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
101.	**Silicosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
102.	**Smallpox.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
103.	**Smallpox vaccine-related adverse events.**	**Telephone.**	**Immediately by telephone.**
104.	**Spotted fever rickettsiosis (Rocky Mountain spotted fever).**	**Electronic disease surveillance system.**	**Within 5 work days.**
105.	**St. Louis encephalitis virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**

106.	***Staphylococcus aureus* infection or colonization, vancomycin-resistant or with intermediate resistance to vancomycin (VRSA or VISA).**	**Electronic disease surveillance system.**	**Within 24 hours.**
107.	**Streptococcal invasive disease (group A), with organism identified in a normally sterile body site.**	**Electronic disease surveillance system.**	**Within 24 hours.**
108.	**Streptococcus pneumoniae (pneumococcus) invasive infection, with organism identified in a normally sterile body site.**	**Electronic disease surveillance system.**	**Within 5 work days.**
109.	**Syphilis (all stages including congenital syphilis and syphilitic stillbirths).**	**Electronic disease surveillance system.**	**Within 24 hours.**
110.	**Tetanus.**	**Electronic disease surveillance system.**	**Within 24 hours.**
111.	**Tickborne disease, excluding Lyme Disease and other conditions listed separately, including disease due to *Borrelia miyamotoi*, Bourbon virus, Heartland virus, etc.**	**Electronic disease surveillance system.**	**Within 24 hours.**
112.	**Toxic shock syndrome, streptococcal and non-streptococcal.**	**Electronic disease surveillance system.**	**Within 24 hours**
113.	**Toxoplasmosis.**	**Electronic disease surveillance system.**	**Within 5 work days.**
114.	**Trichinellosis (trichinosis).**	**Electronic disease surveillance system.**	**Within 5 work days.**
115.	**Tuberculosis suspected or confirmed active disease (all sites).**	**Electronic disease surveillance system.**	**Within 5 work days.**
116.	**Tuberculosis infection, latent.**	**Electronic disease surveillance system.**	**Within 5 work days.**

117.	**Tularemia.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
118.	**Typhoid fever.**	**Electronic disease surveillance system.**	**Within 24 hours.**
119.	**Varicella infection (chickenpox), excluding shingles.**	**Electronic disease surveillance system.**	**Within 5 work days.**
120.	***Vibrio* infection, other than cholera.**	**Electronic disease surveillance system.**	**Within 24 hours.**
121.	**West Nile virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**
122.	**Yellow fever virus infection.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours to the electronic disease surveillance system.**
123.	**Yersiniosis.**	**Electronic disease surveillance system.**	**Within 24 hours.**
124.	**Zika virus infection.**	**Electronic disease surveillance system.**	**Within 24 hours.**

(c) A school nurse shall report to the **[LMRO]** **the Department or a local health department** any unusual increase in the number of absentees among school children. A caregiver at a child care group setting shall report to the **[LMRO]** **the Department or a local health department** any unusual increase in the number of absentees among children attending the child care group setting.

(d) **[A health care facility or health care practitioner providing screening, diagnostic or therapeutic services to patients with respect to cancer shall also report cases of cancer as specified in § 27.31 (relating to reporting cases of cancer).]** **{Reserved}.**

§ 27.22. Reporting of cases by clinical laboratories.

(a) A **[person who is in charge of a]** clinical laboratory in which a laboratory test of a specimen derived from a human body yields **[microscopical, cultural, immunological, serological]** **microscopic, culture, immunologic, serologic**, chemical, **[virologic]** **viral**, nucleic acid (DNA or RNA) or other evidence significant from a public health standpoint of the presence of a disease, infection or condition listed in subsection (b) shall **[promptly]** report the findings**[, no later than the next work day after the close of business on the day on which the test was completed, except as otherwise noted in this chapter]** **in the time and manner specified in subsection (b)**.

(b) **[The diseases, infections and conditions to be reported include the following:**

Amebiasis.

Anthrax.

An unusual cluster of isolates.

Arboviruses.

Botulism—all forms.

Brucellosis.

CD4 T-lymphocyte counts and percentages.

Campylobacteriosis.

Cancer.

Chancroid.

Chickenpox (varicella).

Chlamydia trachomatis infections.

Cholera.

Congenital adrenal hyperplasia (CAH) in children under 5 years of age.

Creutzfeldt-Jakob disease.

Cryptosporidiosis.

Diphtheria infections.

Enterohemorrhagic E. coli 0157 infections, or infections caused by other subtypes producing shiga-like toxin.

Galactosemia in children under 5 years of age.

Giardiasis.

Gonococcal infections.

Granuloma inguinale.

HIV (Human Immunodeficiency Virus).

HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results.

Haemophilus influenzae infections—invasive from sterile sites.

Hantavirus.

Hepatitis, viral, acute and chronic cases.

Histoplasmosis.

Influenza.

Lead poisoning.

Legionellosis.

Leprosy (Hansen's disease).

Leptospirosis.

Listeriosis.

Lyme disease.

Lymphogranuloma venereum.

Malaria.

Maple syrup urine disease (MSUD) in children under 5 years of age.

Measles (rubeola).

Meningococcal infections—invasive from sterile sites.

Mumps.

Pertussis.

Phenylketonuria (PKU) in children under 5 years of age.

Primary congenital hypothyroidism in children under 5 years of age.

Plague.

Poliomyelitis.

Psittacosis (ornithosis).

Rabies.

Respiratory syncytial virus.

Rickettsial infections.

Rubella.

Salmonella.

Shigella.

Sickle cell disease in children under 5 years of age.

Staphylococcus aureus Vancomycin-resistant (or intermediate) invasive dis-ease.

Streptococcus pneumoniae, drug-resistant invasive disease.

Syphilis.

Tetanus.

Toxoplasmosis.

Trichinosis.

Tuberculosis, confirmation of positive smears or cultures, including results of drug susceptibility testing.

Tularemia.

Typhoid.] Unless otherwise set forth in this chapter or otherwise directed by the Department, the following etiologic agents are reportable by clinical laboratories in the time and manner specified:

	Lab findings suggesting current disease, infection or condition:	Manner of reporting to Department:	Timeframe for reporting after test was completed:
1.	Acid fast bacilli, positive smears.	Electronic disease surveillance system.	No later than the next work day.
2.	Adenoviruses.	Electronic disease surveillance system.	No later than the next work day.
3.	*Anaplasma* species.	Electronic disease surveillance system.	No later than the next work day.
4.	Arboviral infection, not otherwise listed.	Electronic disease surveillance system.	No later than the next work day.
5.	*Arenaviruses*, (including Junin, Machupo, Guanarito and Sabia).	Telephone and electronic disease surveillance system.	Immediately by telephone and within 24 hours by electronic disease surveillance system.
6.	Arsenic level greater or equal to 7 micrograms per deciliter (µg/dL) of blood, or 50 micrograms per liter (µg/L) of urine.	Electronic disease surveillance system.	No later than the next work day.

7.	***Aspergillus fumigatus*, azole-resistant.**	**Electronic disease surveillance system.**	**No later than the next work day.**
8.	***Babesia microti.***	**Electronic disease surveillance system.**	**No later than the next work day.**
9.	***Bacillus anthracis* (anthrax).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
10.	***Bacillus cereus* Biovar *anthracis*.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
11.	***Bartonella* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
12.	***Bordetella pertussis* (Pertussis).**	**Electronic disease surveillance system.**	**No later than the next work day.**
13.	***Borrelia burgdorferi* (Lyme disease).**	**Electronic disease surveillance system.**	**No later than the next work day.**
14.	***Borrelia miyamotoi.***	**Electronic disease surveillance system.**	**No later than the next work day.**
15.	***Brucella* species.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
16.	**Bourbon virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
17.	***Burkholderia mallei* and *pseudomallei* (glanders and melioidosis).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**

18.	**Cadmium level greater or equal to 5 micrograms per liter (µg/L) of whole blood, or 3 micrograms per gram (µg/g) of creatinine.**	**Electronic disease surveillance system.**	**No later than the next work day.**
19.	***Campylobacter* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
20.	***Candida auris.***	**Electronic disease surveillance system.**	**No later than the next work day.**
21.	**Carbapenemase-producing organisms, including carbapenem-resistant Enterobacterales, *Pseudomonas* species and *Acinetobacter* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
22.	**Carboxyhemoglobin (COHb) greater or equal to 5% in blood.**	**Electronic disease surveillance system.**	**No later than the next work day.**
23.	**Chikungunya virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
24.	***Chlamydia psittaci* (psittacosis or ornithosis).**	**Electronic disease surveillance system.**	**No later than the next work day.**
25.	***Chlamydia trachomatis*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
26.	**Cholinesterase levels, all results.**	**Electronic disease surveillance system.**	**No later than the next work day.**
27.	***Clostridium botulinum* (botulism) and botulinum toxin.**	**Electronic disease surveillance system.**	**No later than the next work day.**
28.	***Clostridium perfringens* and Clostridial enterotoxin.**	**Electronic disease surveillance system.**	**No later than the next work day.**
29.	***Clostridium tetani* (tetanus).**	**Electronic disease surveillance system.**	**No later than the next work day.**
30.	***Coccidioides* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**

31.	**Coronaviruses, novel, other than COVID-19, including Middle East Respiratory Syndrome virus (MERS-CoV) and the original Severe Acute Respiratory Syndrome virus (SARS-CoV).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
32.	***Corynebacterium diphtheriae* test results indicating acute infection (Diphtheria).**	**Electronic disease surveillance system.**	**No later than the next work day.**
33.	***Coxiella burnetti* (Q fever).**	**Electronic disease surveillance system.**	**No later than the next work day.**
34.	**Creutzfeldt-Jakob disease proteins.**	**Electronic disease surveillance system.**	**No later than the next work day.**
35.	***Cronobacter* species in an infant specimen.**	**Electronic disease surveillance system.**	**Within 24 hours.**
36.	***Cryptosporidium*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
37.	***Cyclospora cayetanensis* (cyclosporiasis).**	**Electronic disease surveillance system.**	**No later than the next work day.**
38.	**Dengue virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
39.	**Eastern equine encephalitis virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
40.	***Ehrlichia* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
41.	***Entamoeba histolytica* (amebiasis).**	**Electronic disease surveillance system.**	**No later than the next work day.**
42.	***Filoviridae* species.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
43.	**Foodborne toxins, including mushroom toxins, ciguatera**	**Electronic disease surveillance system.**	**No later than the next work day.**

	toxins, scombrotoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, staphylococcus enterotoxin, *Bacillus cereus* toxin and others.		
44.	***Francisella tularensis* (tularemia).**	**Electronic disease surveillance system.**	**No later than the next work day.**
45.	**Free-living amoebas, including *Acanthamoeba* species, *Balamuthia mandrillaris*, and *Naegleria fowleri*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
46.	***Giardia lamblia* (or *Giardia duodenalis*).**	**Electronic disease surveillance system.**	**No later than the next work day.**
47.	***Haemophilus ducreyi* (chancroid).**	**Electronic disease surveillance system.**	**No later than the next work day.**
48.	***Haemophilus influenzae* recovered from any normally sterile body site.**	**Electronic disease surveillance system.**	**No later than the next work day.**
49.	**Hantavirus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
50.	**Heartland virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
51.	**Hepatitis A virus, test results indicating acute infection.**	**Electronic disease surveillance system.**	**No later than the next work day.**
52.	**Hepatitis B virus, test results indicating acute, chronic, or perinatal infection.**	**Electronic disease surveillance system.**	**No later than the next work day.**
53.	**Hepatitis B virus, negative surface antigen and nucleic acid tests.**	**Electronic disease surveillance system.**	**No later than the next work day.**
54.	**Hepatitis C virus, test results indicating acute, chronic, or perinatal infection.**	**Electronic disease surveillance system.**	**No later than the next work day.**

55.	**Hepatitis C virus, negative antibody and nucleic acid tests.**	**Electronic disease surveillance system.**	**No later than the next work day.**
56.	**Hepatitis D (delta) virus, test results indicating acute or chronic infection.**	**Electronic disease surveillance system.**	**No later than the next work day.**
57.	**Hepatitis E virus, test results indicating acute or chronic infection.**	**Electronic disease surveillance system.**	**No later than the next work day.**
58.	**Hepatitis, viral, other types.**	**Electronic disease surveillance system.**	**No later than the next work day.**
59.	***Histoplasma capsulatum*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
60.	**Human metapneumovirus**	**Electronic disease surveillance system.**	**No later than the next work day.**
61.	**Influenza virus (all types), positive antigen or nucleic acid result.**	**Electronic disease surveillance system.**	**No later than the next work day.**
62.	***Klebsiella granulomatis*** **(Donovania granulomatis) or Donovan bodies (granuloma inguinale).**	**Electronic disease surveillance system.**	**No later than the next work day.**
63.	**La Crosse encephalitis virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
64.	**Lead results for persons of all ages, including negative results or results below the limit of detection, from venous or capillary blood specimens.**	**Electronic disease surveillance system.**	**No later than the next work day.**
65.	***Legionella*** **species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
66.	***Leptospira interrogans*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
67.	***Listeria monocytogenes*** **or other pathogenic *Listeria* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**

68.	**Lymphogranuloma venereum.**	**Electronic disease surveillance system.**	**No later than the next work day.**
69.	**Marburg virus.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
70.	**Mercury level greater or equal to 2.8 micrograms per deciliter (µg/dL) of blood, or 20 micrograms per liter (µg/L) of urine or 5 micrograms per gram (µg/g) in hair.**	**Electronic disease surveillance system.**	**No later than the next work day.**
71.	**Monkeypox (Mpox) virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
72.	**Mumps virus, test results indicating acute infection.**	**Electronic disease surveillance system.**	**No later than the next work day.**
73.	***Mycobacterium leprae* (leprosy, Hansen's disease).**	**Electronic disease surveillance system.**	**No later than the next work day.**
74.	***Mycobacterium tuberculosis* or tuberculosis complex, by nucleic acid amplification, culture or culture-independent diagnostic test including interferon gamma-release assays (IGRAs).**	**Electronic disease surveillance system.**	**No later than the next work day.**
75.	***Mycobacterium tuberculosis* or tuberculosis complex, all results of drug susceptibility testing.**	**Electronic disease surveillance system.**	**No later than the next work day.**
76.	***Neisseria gonorrhoeae* (Gonorrhea).**	**Electronic disease surveillance system.**	**No later than the next work day.**
77.	***Neisseria meningitidis*, recovered from any normally sterile body site.**	**Electronic disease surveillance system.**	**No later than the next work day.**

78.	**Nontuberculous mycobacteria isolated from an extrapulmonary site.**	**Electronic disease surveillance system.**	**No later than the next work day.**
79.	**Norovirus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
80.	**Orthopox virus, not otherwise listed including vaccinia virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
81.	**Pandrug-resistant organism.**	**Electronic disease surveillance system.**	**No later than the next work day.**
82.	**Parainfluenza virus.**	**Electronic disease surveillance system.**	**No later than next work day.**
83.	***Plasmodium* species (Malaria).**	**Electronic disease surveillance system**	**No later than the next work day.**
84.	**Polio virus, test results indicating acute infection.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
85.	**Powassan virus.**	**Electronic disease surveillance system**	**No later than the next work day.**
86.	**Rabies virus in humans.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
87.	**Respiratory syncytial virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
88.	**Rhinovirus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
89.	**Ricin.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**

90.	***Rickettsia*, including *R. rickettsii* (spotted fever rickettsiosis), *R. akari*. (Rickettsialpox), *R. typhi*, *R. felis*, and *R. prowazekii* (typhus).**	**Electronic disease surveillance system.**	**No later than the next work day.**
91.	**Rubella virus, test results indicating acute infection (German Measles).**	**Electronic disease surveillance system.**	**No later than the next work day.**
92.	**Rubeola virus, test results indicating acute infection (Measles).**	**Electronic disease surveillance system.**	**No later than the next work day.**
93.	**St. Louis encephalitis virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
94.	***Salmonella* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
95.	***Salmonella* Typhi (typhoid fever) or *Salmonella* Paratyphi (paratyphoid fever).**	**Electronic disease surveillance system.**	**No later than the next work day.**
96.	**SARS-CoV-2 (COVID-19).**	**Electronic disease surveillance system.**	**No later than the next work day.**
97.	***Shigella* species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
98.	**Smallpox virus.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
99.	***Staphylococcus aureus* resistant or with intermediate sensitivity to vancomycin (VRSA or VISA).**	**Electronic disease surveillance system.**	**No later than the next work day.**
100.	**Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC) infection, or detection of shiga toxin or shiga toxin genes in a clinical specimen.**	**Electronic disease surveillance system.**	**No later than the next work day.**

101.	***Streptococcus pneumoniae*** **(pneumococcus), recovered from any normally sterile body site.**	**Electronic disease surveillance system.**	**No later than the next work day.**
102.	***Streptococcus pyogenes*****, Group A, recovered from any normally sterile body site.**	**Electronic disease surveillance system.**	**No later than the next work day.**
103.	***Toxoplasma*****.**	**Electronic disease surveillance system.**	**No later than the next work day.**
104.	***Treponema pallidum*** **(syphilis).**	**Electronic disease surveillance system.**	**No later than the next work day.**
105.	***Trichinella*** **species.**	**Electronic disease surveillance system.**	**No later than the next work day.**
106.	**Unusual cluster of isolates, including organisms not explicitly reportable.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
107.	**Varicella zoster virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**
108.	***Vibrio*** **species, including *V. cholerae*, *V. parahaemolyticus*** **and *V. vulnificus*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
109.	**West Nile virus.**	**Electronic disease surveillance system**	**No later than the next work day.**
110.	**Yellow fever virus.**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
111.	***Yersinia enterocolitica*****.**	**Electronic disease surveillance system.**	**No later than the next work day.**
112.	***Yersinia pestis*** **(plague).**	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic**

			disease surveillance system.
113.	***Yersinia pseudotuberculosis*.**	**Electronic disease surveillance system.**	**No later than the next work day.**
114.	***Zaire Ebolavirus.***	**Telephone and electronic disease surveillance system.**	**Immediately by telephone and within 24 hours by electronic disease surveillance system.**
115.	**Zika virus.**	**Electronic disease surveillance system.**	**No later than the next work day.**

(c) The report shall include the following**[, except as provided in subsection (d)]**:

(1) The name, **[age] date of birth, gender, race, ethnicity**, address and telephone number of the person from whom the specimen was obtained.

(2) The date the specimen was collected.

(3) The source of the specimen (such as, **venous, capillary,** serum, stool, CSF, **or** wound) **and the location of the body that the specimen was collected from**.

(4) The name of the test or examination performed and the date it was performed.

(5) The results of the test.

(6) The range of normal values for the specific test performed.

(7) The name, address and telephone number of the **[physician for whom the examination or test was performed] ordering health care practitioner and the facility that ordered the test**.

(7.1) Name and address of employer (for persons occupationally exposed).

(7.2) Pregnancy status of the person from whom the specimen was obtained, if known.

(7.3) The name of the clinical laboratory that performed the test.

(8) Other information requested in case reports or formats specified by the Department.

(d) **[Laboratory test results shall be reported by the person in charge of a laboratory through the appropriate electronic disease surveillance system. Reports of CAH, galactosemia maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell disease and cancer, shall be made in the manner specifically designated in this subchapter. See §§ 27.30 and 27.31 (relating to reporting cases of certain diseases in the newborn; and reporting cases of cancer).]** **{Reserved}.**

(e) **[A clinical laboratory shall submit isolates of salmonella and shigella to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.]** **{Reserved}.**

(f) **[A clinical laboratory shall submit isolates of Neisseria meningitidis obtained from a normally sterile site to the Department's Bureau of Laboratories for serogrouping within 5 work days of isolation.]** **{Reserved}.**

(g) **[A clinical laboratory shall send isolates of enterohemorrhagic E. coli to the Department's Bureau of Laboratories for appropriate further testing within 5 work days of isolation.]** **{Reserved}.**

(h) **[A clinical laboratory shall send isolates of Haemophilus influenzae obtained from a normally sterile site to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.]** **{Reserved}.**

(i) **[The Department, upon publication of a notice in the *Pennsylvania Bulletin*, may authorize changes in the requirements for submission of isolates based upon medical or public health developments when such departure is determined by the Department to be necessary to protect the health of the people of this Commonwealth. The change will not**

remain in effect for more than 90 days after publication unless the Board acts to affirm the change within that 90-day period.] **{Reserved}.**

(j) A clinical laboratory that identifies a reportable pathogen of any of the following using a culture-independent diagnostic test shall culture the organism, when possible, and submit either isolates or specimens to the Department's Bureau of Laboratories within 5 work days of identification:

(1) *Candida auris*.

(2) Carbapenemase-producing organisms.

(3) *Corynebacterium diphtheriae*.

(4) *Haemophilus influenzae*, recovered from any normally sterile body site.

(5) *Listeria monocytogenes*, or other pathogenic *Listeria* species.

(6) *Mycobacterium tuberculosis*, or tuberculosis complex, including *bovis* and *bovis* BCG (all sites).

(7) *Neisseria meningitidis*, recovered from any normally sterile body site.

(8) Coronavirus infection, novel, other than COVID-19, including MERS-CoV and SARS-CoV.

(9) Polio virus, positive viral cultures.

(10) *Salmonella*, all types including Typhi and Paratyphi.

(11) Shigella species.

(12) Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC).

(13) Vaccinia virus.

(14) *Vibrio* species, including *Vibrio cholerae*.

(15) Other cultures or specimens as requested by the Department.

(k) A clinical laboratory shall report reflex culture results for the organisms listed in subsection (j), whether positive or negative.

(l) A clinical laboratory that suspects the presence of any of the following select agents or toxins in a specimen or culture shall contact the Department's Bureau of Laboratories immediately by telephone and shall thereafter submit the specimen or isolate to the Bureau of Laboratories or another laboratory designated by the Bureau of Laboratories.

(1) *Bacillus anthracis* or *Bacillus cereus* Biovar *anthracis*.

(2) *Brucella* species.

(3) *Burkholderia mallei*.

(4) *Burkholderia pseudomallei*.

(5) *Clostridium botulinum*.

(6) Ebola virus.

(7) Filovirus, not otherwise specified.

(8) *Francisella tularensis*.

(9) Marburg virus.

(10) Ricin.

(11) Variola virus.

(12) *Yersinia pestis*.

§ 27.22a. Reporting of select agents or toxins.

(a) A laboratory that possesses, uses or transfers select agents or toxins shall report a detected release, exposure, loss or theft of a select agent or toxin to the Department's Bureau of Laboratories within 1 hour, via telephone call or email, and through the

submission of a written report within 7 days of the incident. The written report shall include the following:

(1) The name, physical address, telephone number and email address of the laboratory.

(2) The name, physical address, telephone number and email address of the officer or person in charge of the laboratory.

(3) The name of the select agent or toxin.

(4) The names of persons potentially exposed to the select agent or toxin.

(5) The quantity of the select agent or toxin suspected or known to have been released, lost or stolen.

(6) A description of the incident, including the time and location that the release, exposure, loss or theft occurred.

(7) An assessment of the severity of the incident.

(8) Other information as requested by the Department.

(b) For the purposes of this section, the term "laboratory" includes a commercial, research or clinical laboratory.

§ 27.23. Reporting of cases by persons [other than health care practitioners, health care facilities, veterinarians or laboratories] in charge of child care group settings.

[Except with respect to reporting cancer, AIDS, CD4 T-lymphocyte counts and percentages, HIV test results or perinatal exposure of a newborn to HIV, HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results, individuals in charge of the following types of group facilities identifying a disease, infection or condition listed in § 27.21a (relating to reporting of cases by health care

practitioners and health care facilities) by symptom, appearance or diagnosis shall make a report within the timeframes required in § 27.21a:

(1) Institutions maintaining dormitories and living rooms.

(2) Orphanages.

(3) Child care group settings.] **To prevent a public health emergency or during a public health emergency, the Department may require that persons in charge of child care group settings report suspected or known cases of the diseases, infections or conditions listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities).**

§ 27.24a. Reporting of cases by veterinarians.

A veterinarian **[is required to report a case, as specified in § 27.4 (relating to reporting cases), only if the veterinarian treats or examines an animal which the veterinarian suspects of having a disease set forth in § 27.35(a) (relating to reporting cases of disease in animals).]** **shall report the following diseases, infections or conditions in animals:**

(1) La Crosse encephalitis virus, by telephone within 5 work days.

(2) Novel influenza A, by telephone within 5 work days.

(3) St. Louis encephalitis virus, by telephone within 5 work days.

(4) Yellow fever virus, by telephone within 5 work days.

(5) An outbreak, public health emergency or unusual disease, infection or condition, in the time and manner set forth in § 27.3 (relating to reporting of outbreaks, public health emergencies and unusual diseases, infections and conditions).

§ 27.29. [Reporting for special research projects.

A person in charge of a hospital or other institution for the treatment of disease shall, upon request of the Department, make reports of a disease or condition for which the Board has

approved a specific study to enable the Department to determine and employ the most efficient and practical means to protect and to promote the health of the people by the prevention and control of the disease or condition. The reports shall be made on forms prescribed by the Department and shall be transmitted to the Department or to local health authorities as directed by the Department.] **{Reserved}.**

DISEASES AND CONDITIONS REQUIRING SPECIAL REPORTING

§ 27.30. Reporting cases of certain diseases in the newborn child.

[Reports of congenital adrenal hyperplasia (CAH), galactosemia, maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism and sickle cell disease shall be made to the Division of Newborn Disease Prevention and Identification, Bureau of Family Health, as specified in Chapter 28 (relating to screening and follow-up for diseases of the newborn) and those provisions of § 27.4 (relating to reporting cases) consistent with Chapter 28 and this section.]

(a) Health care practitioners, health care facilities and clinical laboratories shall report newborn diseases and conditions to the Division of Newborn Screening and Genetics, Bureau of Family Health in accordance with the requirements of the Newborn Child Testing Act (35 P.S. §§ 621—625) and its regulations at 28 Pa. Code Chapter 28 (relating to screening and follow-up for diseases of the newborn).

(b) The Department will maintain an updated list of newborn diseases and conditions that are reportable under the Newborn Child Testing Act and its regulations, on its website.

(c) Cases of Neonatal Abstinence Syndrome shall be reported to the Division of Newborn Screening and Genetics, Bureau of Family Health.

§ 27.31. Reporting cases of cancer and brain-related tumors.

(a) A hospital, clinical laboratory, or other health care facility providing screening, diagnostic or therapeutic services **[for cancer to cancer patients]** **to patients for cancer or brain-related tumors** shall report each case of cancer **or brain-related tumor** to the **[Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and Research]** **Department's electronic cancer registry**, within 180 days of the patient's discharge, if an inpatient or, if an outpatient, within 180 days following diagnosis or initiation of treatment.

(b) A health care practitioner providing screening, diagnostic or therapeutic services to **[cancer]** patients for cancer **or brain-related tumors** shall report each **[cancer]** case to the **[Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and Research]** **Department's electronic cancer registry**, within **[5 work]** **180** days of diagnosis. Cases directly referred to or previously admitted to a hospital or other health care facility providing screening, diagnostic or therapeutic services to **[cancer]** patients **for cancer or brain-related tumors** in this Commonwealth, and reported by those facilities, are exceptions and do not need to be reported by the health care practitioner.

(c) The Department or its authorized representative shall be afforded physical access to all records of **[physicians and surgeons]** **health care practitioners**, hospitals, outpatient clinics, **[nursing homes]** **long-term care nursing facilities** and all other facilities, individuals or agencies providing services to patients which would identify cases of cancer **or brain-related tumors,** or would establish characteristics of the cancer **or brain-related tumors**, treatment of the cancer **or brain-related tumors** or medical status of any identified cancer **or brain-related tumor** patient.

(d) Reports submitted under this section are confidential and may not be open to public inspection or dissemination. Information for specific research purposes may be released in

accordance with procedures established by the Department with the advice of the Pennsylvania Cancer Control, Prevention and Research Advisory Board.

(e) **[Case reports of cancer shall be sent to the Cancer Registry, Division of Health Statistics, Bureau of Health Statistics and Research, unless otherwise directed by the Department.]** **{Reserved}.**

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§ 27.32b. Confidential and anonymous testing.

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(b) Anonymous test results shall be reported in accordance with § 27.32a(b)(2) (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable test results, and HIV genotype test results and perinatal exposure of newborns to HIV). In lieu of the information required in § 27.32a(b)(2)(i), the report of an anonymous test shall include an assigned number preprinted on the HIV **[counseling and]** testing report form. The report shall also include the individual's county of residence.

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§ 27.32c. Partner services relating to HIV and AIDS.

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(b) A person providing an AIDS diagnosis, HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load test results, or HIV genotype test results to an individual shall inform the individual that the Department or a local health department may contact the individual for a voluntary confidential interview to discuss partner services, including counseling, testing, referral**, partner elicitation** and partner notification.

* * * * *

§ 27.32d. Department authority to require complete reporting.

The Department **[will]** **or local health department shall** have access to and may review the patient records of health care practitioners, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of AIDS, or who receive or provide HIV test results, CD4 T-lymphocyte counts or percentages, HIV viral load test results including detectable and undetectable test results or HIV genotype test results. Access and review will enable the Department **or local health department** to conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays and to investigate other reporting problems.

§ 27.32e. Record audits.

(a) The Department **or local health department** may conduct record audits of the records of health care practitioners, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of AIDS or who receive or provide HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results including detectable and undetectable test results, or HIV genotype test results for the purpose of obtaining information allowing the Department **or local health department** to complete HIV, CD4 T-lymphocyte case reports, and viral load and HIV genotyping case reports to aid it in tracking trends in disease and obtaining additional funding for prevention and treatment programs. The Department **or local health department** may audit records going back to January 1, 2000, for this purpose.

(b) The Department **or local health department** may require special reports of persons or entities required to report under this chapter to ensure compliance with this chapter.

§ 27.33. [Reporting cases of sexually transmitted disease.

(a) Reportable sexually transmitted diseases and infections are as follows:

(1) Chancroid.

(2) Chlamydia trachomatis infections.

(3) Gonococcal infections.

(4) Granuloma inguinale.

(5) Lymphogranuloma venereum.

(6) Syphilis.

(b) Health care practitioners and health care facilities shall make case reports of these diseases to the LMRO where the case is diagnosed or identified.

(c) A clinical laboratory making a case report by paper shall make the report to the LMRO where the case is diagnosed or identified. A clinical laboratory making a case report electronically shall make the report to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.] **{Reserved}.**

§ 27.33a. Reporting treatment for sexually transmitted diseases and tuberculosis.

(a) ***Report requirements.*** **In addition to the reporting requirements under § 27.21a (relating to reporting of health care practitioners and health care facilities), a health care practitioner or health care facility shall report the treatment provided to all suspected or confirmed cases of tuberculosis and the following sexually transmitted diseases through the Department's electronic disease surveillance system or the local health department:**

(1) Chancroid.

(2) Chlamydia trachomatis infection.

(3) Gonococcal infection.

(4) Granuloma inguinale.

(5) Lymphogranuloma venereum.

(6) Syphilis.

(b) ***Timing of report.*** **The treatment report under subsection (a) shall be submitted within 5 work days and shall include the date of treatment, medication prescribed or administered, and the dose of medication.**

(c) ***Patient records.*** **In addition to the reporting requirements under § 27.21a (relating to reporting of health care practitioners and health care facilities), a health care practitioner or health care facility shall, upon request, provide records related to tuberculosis evaluation and treatment of a patient by facsimile or other means acceptable to the Department within 48 hours.**

§ 27.33b. Reporting cases of animal bites, scratches or contamination of open wounds or mucous membranes.

A health care practitioner or a health care facility shall report human exposure or suspected human exposure to saliva or neural tissue from a mammal through a bite, scratch or contamination of an open wound or mucous membrane to the local health department serving the geographical area in which the case is identified or the Department's district office or state health center in that region. The report shall be sent via facsimile within 24 hours on a form prescribed by the Department or by other means acceptable to the Department.

§ 27.34. [Reporting cases of lead poisoning.

(a) ***Reporting by clinical laboratories.***

(1) A clinical laboratory shall report all blood lead test results on both venous and capillary specimens for persons under 16 years of age to the Childhood Lead Poisoning Prevention Program, Division of Maternal and Child Health, Bureau of Family Health.

(2) A clinical laboratory shall report an elevated blood lead level in a person 16 years of age or older to the Division of Environmental Health Epidemiology, Bureau of Epidemiology or to other locations as designated by the Department. An elevated blood lead level is defined by the National Institute For Occupational Safety And Health (NIOSH). As of January 26, 2002, NIOSH defines an elevated blood lead level as a venous blood lead level of 25 micrograms per deciliter (µg/dL) or higher. The Department will publish in the *Pennsylvania Bulletin* any NIOSH update of the definition within 30 days of NIOSH's notification to the Department.

(3) A clinical laboratory which conducts blood lead tests of 100 or more specimens per month shall submit results electronically in a format specified by the Department.

(4) A clinical laboratory which conducts blood lead tests of less than 100 blood lead specimens per month shall submit results either electronically or by hard copy in the format specified by the Department.

(5) A laboratory which performs blood lead tests on blood specimens collected in this Commonwealth shall be licensed as a clinical laboratory and shall be specifically approved by the Department to conduct those tests.

(6) Blood lead analyses requested for occupational health purposes on blood specimens collected in this Commonwealth shall be performed only by laboratories which are licensed and approved as specified in paragraph (5), and which are also approved by the

Occupational Safety and Health Administration of the United States Department of Labor under 29 CFR 1910.1025(j)(2)(iii) (relating to lead).

(7) A clinical laboratory shall complete a blood lead test within 5 work days of the receipt of the blood specimen and shall submit the case report to the Department by the close of business of the next work day after the day on which the test was performed. The clinical laboratory shall submit a report of lead poisoning using either the hard-copy form or electronic transmission format specified by the Department.

(8) When a clinical laboratory receives a blood specimen without all of the information required for reporting purposes, the clinical laboratory shall test the specimen and shall submit the incomplete report to the Department

(b) ***Reporting by health care practitioners or health care facilities.*** **A health care practitioner or health care facility shall report all cases of lead poisoning for persons under 16 years of age and pregnant women to the Lead Poisoning Prevention Program, Child and Adult Health Services Division, Bureau of Family Health. A case of lead poisoning shall be a lead level of 20 µg/dL or greater or a persistent elevated blood lead level (2 or more venous blood lead levels of 15 to 19 µg/dL (inclusive) at least three months apart).]**

{Reserved}.

§ 27.35. Reporting cases of disease in animals.

(a) The following diseases, infections and conditions in animals are reportable to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology, as specified in § 27.4 (relating to reporting cases) within 5 work days after being identified:

Anthrax.

Arboviruses.

Brucellosis.

Plague.

Psittacosis.

Rabies.

Transmissible Spongiform Encephalopathies.

Tuberculosis.

Tularemia.

Any disease, infection or condition covered by § 27.3(b) (relating to reporting outbreaks and unusual diseases, infections and conditions).

(b) This chapter applies only to animals having or suspected of having one of the diseases, infections or conditions listed in subsection (a).

§ 27.36. Reporting immunization delivery.

(a) Unless a patient has declined the reporting of an immunization in writing, a health care practitioner, health care facility or individual authorized by law to administer immunizations shall report each immunization administration in all counties of this Commonwealth, except Philadelphia County, to the Department's designated immunization information system.

(b) The vaccine administration report shall be made within thirty days of administration, unless the Department requires it earlier during a public health emergency or a different timeframe is required by law.

(c) The report shall contain the following patient information:

(1) Name (first, middle and last).

(2) Date of birth.

(3) Gender.

(4) Address.

(5) Race.

(6) Ethnicity.

(d) The report shall contain the following vaccine information:

(1) Type of vaccine.

(2) Manufacturer.

(3) Lot number.

(4) Expiration date.

(5) Vaccine administration code (CVX).

(6) Date of vaccine administration.

(7) Route of vaccine administration.

§ 27.37. Reporting birth defects and congenital anomalies.

(a) Effective _____ (*Editor's Note*: The blank refers to the date 30 days after publication of a notice in the *Pennsylvania Bulletin*, consistent with the launch of the birth defects registry.) a health care practitioner and a health care facility shall report through the Department's birth defects registry a case of the following birth defects and congenital anomalies within 180 work days of diagnosis:

(1) Congenital malformations of the nervous system.

(2) Congenital malformations of eye, ear, face and neck.

(3) Congenital malformations of the circulatory system.

(4) Congenital malformations of the respiratory system.

(5) Cleft lip and cleft palate.

(6) Other congenital malformations of the digestive system.

(7) Congenital malformations of genital organs.

(8) Congenital malformations of the urinary system.

(9) Congenital malformations and deformations of the musculoskeletal system.

(10) Other congenital malformations.

(11) Chromosomal abnormalities not elsewhere classified.

(12) Abnormal findings on neonatal screening.

(b) A reportable birth defect or congenital anomaly, under this section, includes a birth defect or anomaly diagnosed in the following:

(1) Infants who are born alive and have a birth defect or anomaly diagnosed before their first birthday. This includes infants who are born alive but die before their first birthday and are diagnosed with a birth defect or anomaly at the time of death.

(2) Fetuses that are not born alive but have completed 19 weeks of gestation. In the absence of a gestational age estimate, a congenital anomaly in a fetus that is not born alive shall be reported if the fetus had a weight of at least 500 grams.

(c) The reporting requirements of this section apply to each infant or fetus born, expelled or extracted.

REPORTING BY LOCAL [MORBIDITY REPORTING OFFICES] HEALTH DEPARTMENTS

§ 27.41a. [Reporting by local morbidity reporting offices of case reports received.

An LMRO that is not one of the Department's district offices shall report a case that has been reported to it to the district office for the State health district in which it is located, or

to the central office when this chapter directs that reports are to be filed with that office.]

{Reserved}.

§ 27.42a. Reporting by local [morbidity reporting offices] health departments of completed case investigations.

[An LMRO that is not one of the Department's district offices shall submit, on a weekly basis, a case investigation report of the information from each case investigation which has resulted in confirmation of the incidence of a reportable disease, infection or condition. The report shall be submitted to the appropriate Department office as follows in a format and within the length of time set forth in this chapter:

(1) *AIDS.* To the HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

(2) *Chickenpox, diphtheria, measles, mumps, pertussis, polio, rubella, and tetanus.* To the Division of Immunizations, Bureau of Communicable Diseases.

(3) *Chancroid, chlamydia trachomatis infections, gonococcal infections, granuloma inguinale, lymphogranuloma venereum, syphilis and tuberculosis.* To the Division of Tuberculosis and Sexually Transmitted Diseases, Bureau of Communicable Diseases.

(4) *Other reportable diseases and conditions.* To the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.]

(a) A local health department shall submit through the Department's electronic disease surveillance system or other means acceptable to the Department a complete case investigation report within seven days of the report's completion.

(b) The report must contain the information from each case investigation that has resulted in confirmation of any disease, infection or condition that is required to be

reported under this chapter.

§ 27.43a. Reporting by local [morbidity reporting offices] health departments of outbreaks [and selected diseases].

(a) **[An LMRO that is not one of the Department's district offices by telephone on the same day that the outbreak is reported or otherwise made known to it, as follows:**

(1) ***AIDS.*** **To the HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.**

(2) ***Chancroid, chlamydia trachomatis infections, gonococcal infections, granuloma inguinale, lymphogranuloma venereum, syphilis and tuberculosis.*** **To the Division of Tuberculosis and Sexually Transmitted Diseases, Bureau of Communicable Diseases.**

(3) ***Chickenpox, diphtheria, measles, mumps, pertussis, polio, rubella and tetanus.*** **To the Division of Immunizations, Bureau of Communicable Diseases.**

(4) ***Other reportable diseases and conditions.*** **To the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.] {Reserved}.**

(b) **[An LMRO that is not one of the Department's district offices shall report by telephone on the same day any of the following diseases is reported or otherwise made known to it, as follows:**

(1) ***Diphtheria, measles, pertussis and polio.*** **To the Division of Immunizations, Bureau of Communicable Diseases.**

(2) ***Anthrax, arbovirus disease, cholera, enterohemorrhagic Escherichia coli, hantavirus pulmonary syndrome, food borne botulism, Haemophilus influenzae invasive disease in a child under 15 years of age, hemorrhagic fever, hepatitis E, human rabies, Legionellosis,***

plague, smallpox, typhoid fever and yellow fever. **To the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.]** **{Reserved}.**

(c) A local health department shall report an outbreak, public health emergency or unusual occurrence of a disease, infection or condition to the Department in the time and manner specified in § 27.3 (relating to reporting outbreaks, public health emergencies and unusual diseases, infections and conditions).

Subchapter C. [QUARANTINE AND ISOLATION] DISEASE CONTROL MEASURES GENERAL PROVISIONS

§ 27.60. Disease control measures.

(a) The Department or local health authority shall direct isolation of a person or an animal with a communicable disease**, [or]** infection **or condition**; surveillance, segregation, quarantine or modified quarantine of contacts of a person or an animal with a communicable disease**, [or]** infection **or condition**; and any other disease control measure the Department or the local health authority considers to be appropriate for the surveillance**, prevention, containment or mitigation** of disease, when the disease control measure is necessary to protect the public from the spread of infectious agents **or toxins**.

(b) The Department and local health authority will determine the appropriate disease control measure based upon the disease**, [or]** infection **or condition**, the patient's circumstances, the type of facility available **if relevant** and any other available information relating to the patient and the disease**, [or]** infection **or condition**.

(c) If a local health authority is not **[an LMRO] a local health department**, it shall consult with and receive approval from the Department prior to taking any disease control measure.

§ 27.60a. Investigation of cases, outbreaks, public health emergencies and unusual occurrences of diseases, infections and conditions.

(a) The Department or local health authority may investigate any case, outbreak, public health emergency, and unusual occurrences of diseases, infections and conditions.

(b) The Department or local health authority may enter an apartment, building, health care facility, school, college or university, or other location as necessary to conduct its investigation under this chapter if the representative presents documentation to establish that they are an authorized representative of the Department or the local health authority.

(c) A person may not obstruct or interfere with, the Department or local health authority's investigation under this chapter.

§ 27.60b. Contact tracing and partner services, generally.

(a) The Department or local health authority may during its investigation under § 27.60a (relating to investigation) enter an apartment, building, health care facility, school, college or university, or other location as necessary to carry out contract tracing or partner services.

(b) A person may not obstruct or interfere, with the Department or local health authority conducting contract tracing or partner services under this section.

§ 27.60c. Contact tracing and partner services in schools.

(a) A school shall provide the Department or local health authority with reasonable and timely access to a person for the purpose of contact tracing or partner services, including access when classes are in session or at any other time the person is present at school, on school premises or attending a school function.

(b) A person, including an employee or official of a school, shall permit the Department or local health authority to meet and speak with a student or other person in private, and may not interfere with the student or other person's ability to exercise their right to give consent under 35 P.S. § 10103.

(c) A person, including an employee or official of a school, may not obstruct or interfere, with the Department or local health authority conducting contract tracing or partner services under this section.

§ 27.60d. Partner services relating to HIV, AIDS and other sexually transmitted and related diseases.

A health care practitioner or other person, including an employee or official of a health care facility or community-based organization, providing sexually transmitted disease, HIV or related test results to a patient shall inform the patient that the Department or a local health authority may contact the patient for a voluntary confidential interview to discuss partner services.

§ 27.60e. Confidential review of patient medical records.

(a) In the course of conducting an investigation, the Department or local health authority, shall have access to and may conduct a confidential review of patient medical records maintained by health care practitioners, hospitals and other health care facilities. Copies of medical records may be requested by the Department or local health authority and shall be transmitted electronically in a secure manner acceptable to the Department or local health authority.

(b) A person may not obstruct or interfere with, the review of patient medical records by the Department or local health authority.

§ 27.61. Isolation.

[When the isolation of a person or animal that is suspected of harboring an infectious agent is appropriate, the Department or local health authority shall cause the isolation to be done promptly following receipt of the case report.] **The Department or local health authority will, when deemed necessary, direct that a person or animal be isolated until no longer capable of causing illness in others when the person or animal is known or strongly suspected to have an illness due to a chemical, biologic or radiologic agent capable of causing illness in others.**

(1) If the local health authority is not **[an LMRO]** **a local health department**, the local health officer shall consult with and receive approval from the Department prior to requiring isolation.

(2) If more than one jurisdiction is involved, the local health officer shall cause a person or animal to be isolated only after consulting with and receiving approval from the Department.

(3) The Department or local health authority **[shall ensure that]** **will provide** **instructions [are given]** to the case or persons responsible for the care of the case and to members of the household or appropriate living quarters**[, defining the area within which the case is to be isolated and identifying the]** **where the case is located. The instructions will indicate the location where the case is to be isolated and will relay the** measures to be taken to prevent the spread of disease.

§ 27.65. Quarantine.

If the disease is one which the Department, or a local health [**authority which is also an LMRO]** **department**, determines to require the quarantine of contacts**, person or animal,** in addition to isolation of the case, the Department or local health **[officer of the LMRO]** **department** shall determine which contacts shall be **[quarantined]** **in quarantine**, specify the

place to which they shall be **[quarantined] in quarantine**, and issue appropriate instructions. **The instructions will indicate when the contacts may be released from quarantine and will relay the measures to be taken to prevent the spread of disease.**

(1) When any other local health authority is involved, the local health officer shall **[quarantine contacts] place contacts in quarantine** only after consulting with and receiving approval from the Department.

(2) The Department or local health officer shall ensure that provisions are made for the medical observation of the contacts as frequently as necessary during the quarantine period **and will ensure that appropriate disease prevention and control measures are being followed**.

§ 27.66. Placarding.

Whenever the Department or a local health officer has reason to believe that a case, a contact or others will not fully comply with the isolation or quarantine as required for the protection of the public health and the Department or local health officer deems it necessary to use placards, placards may be utilized. Placards may be utilized by a local health officer of a local health authority that is not **[an LMRO] a local health department** only if the specific use is approved by the Department.

§ 27.67. Movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department.

(a) A person or animal subject to isolation or quarantine by action of a local health authority or the Department may be removed to another location only with permission of the local health authority or the Department. If the local health authority is not **[an LMRO] a local health department**, the local health authority shall consult with and receive approval from the

Department prior to permitting removal. Permission for removal may be given by the Department if the local health officer is not available.

(b) Removal of a person or animal under isolation or quarantine by action of the Department or a local health authority, from the jurisdiction of the Department or a local health authority to **[the]** **another** jurisdiction **[of the Department or another local health authority]** may occur only with permission of the Department, if it is involved, and with the permission of the local health authorities concerned. If both of the local health authorities involved are not **[LMROs]** **local health departments**, the local health authorities shall consult with and receive approval from the Department prior to permitting removal. Permission for removal may be given by the Department if a local health officer from whom permission would otherwise be required is not available.

(c) Interstate transportation to or from this Commonwealth of a person or animal under isolation or quarantine may be made only with permission of the Department **and a local health department if it is involved**.

(d) Transportation of a person or animal under isolation or quarantine shall be made by private conveyance or as otherwise ordered by the local health authority or the Department. If the local health authority is not **[an LMRO]** **a local health department**, it shall consult with the Department prior to issuing an order. The sender, the receiver and the transporter of the person or animal shall be responsible **[to take due care]** **for following isolation or quarantine instructions** to prevent the spread of the disease.

(e) When a person or animal under isolation or quarantine is transported, isolation or quarantine shall be **[resumed]** **completed** for the period of time required for the specific disease immediately upon arrival of the person or animal at the point of destination.

§ 27.68. Release from isolation or quarantine.

The Department or a local health authority **[may order]** **that ordered** a person or animal **[isolated or quarantined under the direction of the Department or to the appropriate health authority be released]** **into isolation or quarantine may release that person or animal** from isolation or quarantine when the **[Department or the local health]** **appropriate** authority determines that the person or animal no longer presents a public health threat. If the local health authority involved is not **[an LMRO]** **a local health department**, it shall consult with, and receive approval from, the Department prior to making the order.

§ **27.69. Laboratory analysis.**

Whenever a laboratory specimen is to be examined for the presence of etiologic **[organisms]** **agents** to determine the duration of isolation or quarantine or to determine the eligibility of a person or animal for release from isolation or quarantine, the specimen shall be examined in a laboratory **[approved by the Department to conduct that type of examination]** **authorized to conduct this type of examination under applicable State and Federal law**.

COMMUNICABLE DISEASES IN [CHILDREN AND STAFF ATTENDING SCHOOLS AND CHILD CARE GROUP SETTINGS] **FOOD HANDLERS, HEALTH CARE PRACTITIONERS, STUDENTS IN SCHOOLS, COLLEGES AND UNIVERSITIES, CHILDREN IN A CHILD CARE GROUP SETTING, AND PERSONS WHO HAVE DIRECT CONTACT WITH STUDENTS IN A SCHOOL, COLLEGE OR UNIVERSITY OR CHILDREN IN A CHILD CARE GROUP SETTING.**

§ 27.71. [Exclusion of children, and staff having contact with children, for specified diseases and infectious conditions.

A person in charge of a public, private, parochial, Sunday or other school or college shall exclude from school a child, or a staff person, including a volunteer, who has contact with children, who is suspected by a physician or the school nurse of having any of the communicable diseases, infections or conditions. Readmission shall be contingent upon the school nurse or, in the absence of the school nurse, a physician, verifying that the criteria for readmission have been satisfied. The diseases, the periods of exclusion and the criteria for readmission are as follows:

(1) ***Diphtheria.*** **Two weeks from the onset or until appropriate negative culture tests.**

(2) ***Measles.*** **Four days from the onset of rash. Exclusion may also be ordered by the Department as specified in § 27.160 (relating to special requirements for measles).**

(3) ***Mumps.*** **Nine days from the onset or until subsidence of swelling.**

(4) ***Pertussis.*** **Three weeks from the onset or 5 days from institution of appropriate antimicrobial therapy.**

(5) Rubella. Four days from the onset of rash.

(6) ***Chickenpox.*** **Five days from the appearance of the first crop of vesicles, or when all the lesions have dried and crusted, whichever is sooner.**

(7) ***Respiratory streptococcal infections including scarlet fever.*** **At least 10 days from the onset if no physician is in attendance or 24 hours after institution of appropriate antimicrobial therapy.**

(8) ***Infectious conjunctivitis (pink eye).*** **Until judged not infective; that is, without a discharge.**

(9) ***Ringworm.*** **The person shall be allowed to return to school, child care or other group setting immediately after the first treatment, if body lesions are covered. Neither scalp nor body lesions that are dried need to be covered.**

(10) ***Impetigo contagiosa.*** **Twenty-four hours after the institution of appropriate treatment.**

(11) ***Pediculosis capitis.*** **The person shall be allowed to return to either the school, child care or other group setting immediately after first treatment. The person shall be reexamined for infestation by the school nurse, or other health care practitioner, 7 days posttreatment.**

(12) ***Pediculosis corpora.*** **After completion of appropriate treatment.**

(13) ***Scabies.*** **After completion of appropriate treatment.**

(14) ***Trachoma.*** **Twenty-four hours after institution of appropriate treatment.**

(15) ***Tuberculosis.*** **Following a minimum of 2 weeks adequate chemotherapy and three consecutive negative morning sputum smears, if obtainable. In addition, a note from the attending physician that the person is noncommunicable shall be submitted prior to readmission.**

(16) ***Neisseria meningitidis.*** **Until judged noninfective after a course of rifampin or other drug which is effective against the nasopharyngeal carriage state of this disease, or until otherwise shown to be noninfective.]** **{Reserved}.**

§ 27.71a. Exclusion and readmission requirements for specified diseases, infections and conditions of food handlers, health care practitioners, schools, colleges and universities, child care group settings, and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting.

(a) A person in charge of a school, college, university or child care group setting shall adhere to the following exclusion and readmission requirements for persons, and direct contacts of persons, attending, working or volunteering in classes, programs or extracurricular activities who are suspected or confirmed by a health care practitioner acting within the scope of their practice to have the specified disease, infection or condition:

	Disease, infection or condition	*Requirements*
1.	***Amebiasis.***	**(i) A person with amebiasis shall be excluded from child care group settings until the etiological organism has been eradicated, as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as an ova and parasite exam. If antiparasitic treatment has been given, the specimens may not be collected until 48 hours after the last dose of treatment was taken.** **(ii) A person who is a household contact of an individual with amebiasis shall be excluded from attending, working or volunteering at child care group settings until the contact has two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed**

acceptable to the Department. If the household contact received antiparasitic treatment, the specimens may not be collected until 48 hours after the last dose of treatment was taken.

(iii) A toilet-trained person shall be excluded from school settings if their amebiasis-associated diarrhea is causing uncontrolled bowel movements.

(iv) A toilet-trained person shall be readmitted to school when they regain control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day.

2. ***Campylobacter*.**

(i) A diapered child with campylobacter-associated diarrhea shall be excluded from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the time in the program day or the child's stool contains blood or mucus.

(ii) A toilet-trained person shall be excluded from school and child care group settings if the person's campylobacter-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when the child's stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when the person regains control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day.

(iv) A diapered child or toilet-trained person with diarrhea containing blood or mucous may not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.

3. *C. difficile.*

(i) A diapered child with *C. difficile*-associated diarrhea shall be excluded from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above their normal amount during the time in the

program day or the child's stool is black or contains blood or mucus.

(ii) A toilet-trained person shall be excluded from school and child care group settings if the person's *C. difficile*-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when the child's stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day.

(iv) A diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous may not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.

4. ***Conjunctivitis, infectious.*** **A person with infectious conjunctivitis shall be excluded from school and child care group settings if the person has a fever or behavior change.**

5. ***COVID-19.*** **A person with COVID-19 shall be excluded from school, college, university and child care group settings if the person is experiencing a fever and behavior changes, or a fever in combination with any sign or symptom of respiratory illness. The person shall be readmitted to school, college, university or child care group settings 24 hours after the resolution of fever without the use of fever reducing medications.**

6. ***Cryptosporidiosis.***

(i) A diapered child with cryptosporidiosis-associated diarrhea shall be excluded from school and child care group settings if their stool cannot be contained in a diaper, their stool frequency exceeds two stools above their normal amount during the time in the program day or their stool contains blood or mucus.

(ii) A toilet-trained person shall be excluded from school and child care group settings if their cryptosporidiosis-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when their stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when they regain control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day.

(iv) A toilet-trained person or diapered child with diarrhea containing blood or mucous may not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.

7. ***Diphtheria.***

(i) A person with diphtheria shall be excluded from school and child care group settings until the earlier of the following: 14 days after the onset of symptoms or after a health care practitioner acting within the scope of their practice has confirmed an appropriate negative culture test.

(ii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for diphtheria from a school or child care group setting until the person provides proof that the person is not susceptible, receives a vaccine for diphtheria, or when no cases of diphtheria have occurred in the specific school or child care group setting for 14 days. A person susceptible for diphtheria includes a person who: presents no history of four age-appropriate doses of diphtheria vaccine while 15 months of age or older; does not have a diagnosis of diphtheria disease as set forth in a written record from a health care practitioner acting within the scope of their practice; does not demonstrate serological evidence of diphtheria immunity (the presence of antibodies to diphtheria determined by an enzyme-linked immunosorbent assay

test or other comparable test); and was born before December 31, 1956.

8. ***Giardiasis.***

(i) A diapered child with giardiasis-associated diarrhea shall be excluded from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above their normal amount during the time in the program day or the child's stool contains blood or mucus.

(ii) A toilet-trained person shall be excluded from school and child care group settings if the person's giardiasis-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when the child's stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day.

		(iv) A diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous may not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.
9.	***Haemophilus influenzae (H. flu) or other invasive H. flu disease.***	**A person with H. flu meningitis or other invasive H. flu disease shall be excluded from school and child care group settings until 24 hours after initiation of medication that is effective against the nasopharyngeal carriage stage of this disease.**
10.	***Hepatitis A, viral hepatitis unspecified or jaundice of unspecified etiology.***	**A person with hepatitis A, unspecified viral hepatitis, or jaundice of an unspecified etiology shall be excluded from school and child care group settings until one week following the onset of jaundice, or two weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a health care practitioner acting within the scope of their practice.**
11.	***Herpes Simplex.***	**(i) Exclusion of a person with herpes simplex is not necessary unless the person has an ulcer or vesicle inside the mouth and cannot control drooling. The person shall be readmitted to school or child care group settings when**

drooling can be controlled, or there are no ulcers or vesicles present in the person's mouth.

(ii) Athletes participating in sports may not participate in practice or any sporting event until all blisters are fully scabbed over, and there are no new blisters and no swollen lymph nodes near the skin lesions.

12. ***Impetigo.*** **Exclusion of a person with impetigo is not necessary before the end of the program day if the lesions are washed and covered upon discovery. After the end of the program day, the person shall confer with a health care practitioner acting within the scope of their practice to confirm or deny a diagnosis of impetigo before readmission. If the diagnosis is confirmed, the person shall be readmitted the day after treatment has begun, so long as all lesions are covered until dry.**

13. ***Influenza.*** **A person with influenza shall be excluded from school, college, university or child care group settings if the person is experiencing a fever and behavioral change, or a fever in combination with any sign or symptom of respiratory illness. The person shall be readmitted to**

school, college, university or child care group settings 24 hours after the resolution of fever without the use of fever reducing medication.

14. ***Lice (head or body).*** **Exclusion of a person with head or body lice is not necessary before the end of the program day. The person shall be readmitted once treatment has begun. Activities involving shared clothing or soft toys and head-to-head exposure with others shall be avoided until there are no lice or nits present.**

15. ***Measles.*** **(i) A person with measles shall be excluded from school, college, university or child care group settings until four days after the day of rash onset, and any fever must have resolved at least 24 hours prior to be considered for readmission.**

(ii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for measles from a school, college, university or child care group setting until the person provides proof that they are not susceptible, receives a vaccine for measles, or when no cases of measles have

		occurred in the specific school, college, university or child care group setting for 21 days. A person susceptible for measles includes a person who: presents no history of two age-appropriate doses of measles vaccination while 12 months of age or older, with the doses given at least 1 month apart; does not have a diagnosis of measles disease as set forth in a written record from a health care practitioner acting within the scope of their practice; does not demonstrate serological evidence of measles immunity (the presence of antibodies to measles determined by a hemagglutination inhibition test or other comparable test); and was born before December 31, 1956.
16.	***Meningococcal meningitis, meningococcemia or infectious meningitis.***	**A person with meningococcal meningitis, meningococcemia, or infectious meningitis shall be excluded from school and child care group settings until 24 hours after initiation of medication that is effective against the nasopharyngeal carriage stage of this disease, or until the person is judged noninfectious by a health care practitioner acting within the scope of their practice.**

17.	***Mononucleosis.***	**Exclusion of a person with mononucleosis is not necessary. If a person with mononucleosis has an enlarged spleen, the person may not participate in contact sports until this symptom resolves.**
18.	***Methicillin-resistant Staphylococcus aureus (MRSA).***	**Exclusion of a person with MRSA is not necessary, unless directed by a health care practitioner acting within the scope of their practice, so long as the infected skin is covered with a clean, dry bandage to prevent others and objects from coming into contact with the infected skin. The bandage shall be inspected frequently and changed before drainage is visible through the bandage.**
19.	***Mumps.***	**(i) A person with mumps shall be excluded from school and child care group settings until the earlier of the following: complete subsidence of swelling, or 5 days after the onset of swelling.** **(ii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for mumps from a school or child care group setting until the person provides proof that the**

person is not susceptible, receives a vaccine for mumps, or when no cases of mumps have occurred in the specific school or child care group setting for 26 days. A person susceptible for mumps includes a person who: presents no history of two age-appropriate doses of mumps vaccination while 12 months of age or older; does not have a history of mumps disease as set forth in a written record from a health care practitioner acting within the scope of their practice; does not demonstrate serological evidence of mumps immunity (the presence of antibody to mumps determined by an enzyme-linked immunosorbent assay test or a viral neutralization test); and was born before December 31, 1956.

20. ***Norovirus.*** **(i) A diapered child with norovirus-associated diarrhea shall be excluded from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above their normal amount during the time in the program day or the child's stool contains blood or mucus.**

(ii) A toilet-trained person shall be excluded from school and child care group settings if the person's norovirus-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when the child's stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day.

(iv) A diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous may not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.

21. ***Pertussis (whooping cough.***

(i) A person with pertussis shall be excluded from school and child care group settings until the earlier of the following: 5 days from the initiation of appropriate antimicrobial therapy, or 21 days after the day of cough onset if untreated.

(ii) A person who is coughing and has had close contact with a case of pertussis shall be excluded from school and child care group settings until the earlier of the following: a health care practitioner acting within the scope of their practice has determined that the person has a diagnosis other than pertussis, the person has completed 5 days of appropriate antimicrobial therapy, or 21 days have passed since cough onset if untreated.

(iii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for pertussis from a school and child care group setting until the person provides proof that they are not susceptible, receives a vaccine for pertussis, or when no cases of pertussis have occurred in the specific school or child care group setting for 21 days. A person susceptible for pertussis includes a person who: presents no history of four age-appropriate doses of pertussis vaccination while 15 months of age or older; does not have a diagnosis of pertussis as set forth in a written record from a health care practitioner acting within the scope of their practice; does not demonstrate

serological evidence of pertussis immunity (the presence of antibodies to pertussis determined by an enzyme-linked immunosorbent assay test or other comparable test); and was born before December 31, 1956.

22. *Poliomyelitis.*

(i) A person with poliomyelitis shall be excluded from school and child care group settings until the etiological organism has been eradicated, as proven by three negative stool specimens collected 24 hours apart, on 3 consecutive days, as verified by an appropriate clinical laboratory.

(ii) A person with flu-like symptoms, or meningitis, that has had close contact with a case of poliomyelitis shall be excluded from school and child care group settings for a minimum of 7 days after the person's last exposure. The person shall be readmitted if the person obtains: two consecutive negative stool specimens three days after the person's last contact, with 24 to 48 hours between samples, as verified by an appropriate clinical laboratory.

23. ***Rotavirus.***

(i) A diapered child with rotavirus-associated diarrhea shall be excluded from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above the child's normal amount during the time in the program day or the child's stool contains blood or mucus.

(ii) A toilet-trained person shall be excluded from school and child care group settings if the person's rotavirus-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when the child's stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day.

(iv) A diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous may

not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.

24. *Rubella.*

(i) A person with rubella shall be excluded from school and child care group settings for 7 days after the onset of the rash.

(ii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for rubella from a specific school and child care group setting until the person provides proof that they are not susceptible, receives a vaccine for rubella, or when no cases of rubella have occurred in the specific school or child care group setting for 21 days. A person susceptible for rubella includes a person who: presents no history of one age-appropriate dose of rubella vaccination while 12 months of age or older; does not have a diagnosis of rubella disease as set forth in a written record from a health care practitioner acting within the scope of their practice; does not demonstrate serological evidence of rubella immunity (the presence of antibodies to rubella determined by the enzyme-linked

immunosorbent assay test or comparable test); and was born before December 31, 1956.

25. ***Salmonella.***

(i) A diapered child with salmonella-associated diarrhea shall be excluded from school and child care group settings if the child's stool cannot be contained in a diaper, the child's stool frequency exceeds two stools above their normal amount during the time in the program day or the child's stool contains blood or mucus.

(ii) A toilet-trained person shall be excluded from school and child care group settings if the person's salmonella-associated diarrhea is causing uncontrolled bowel movements.

(iii) A diapered child shall be readmitted when the child's stool is contained by a diaper (even if the stool remains loose). A toilet-trained person shall be readmitted when the person regains control of bowel movements, and when stool frequency is no more than two stools above normal for that person during the program day.

		(iv) A diapered child or toilet-trained person with diarrhea that is black or contains blood or mucous may not be readmitted unless cleared by a health care practitioner acting within the scope of their practice.
26.	***Scabies.***	**Exclusion of a person with scabies is not necessary before the end of the program day. The person with a suspected infection shall confer with a health care practitioner acting within the scope of their practice to confirm or deny a diagnosis of scabies before readmission. If the diagnosis is confirmed, the person shall be readmitted once the first course of treatment is complete.**
27.	**Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC).**	**(i) A person with a STEC infection shall be excluded from child care group settings until the etiological organism has been eradicated, as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or a culture-independent diagnostic test. If antibacterial treatment has been given,**

the specimens may not be collected until 48 hours after the last dose of treatment was taken.

(ii) A person who is a household contact of an individual with a STEC infection shall be excluded from child care group settings until the contact has obtained two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or by a culture-independent diagnostic test. If the contact received antibacterial treatment, the specimens may not be collected until 48 hours after the last dose of treatment was taken.

(iii) A toilet-trained person shall be excluded from school settings if their STEC-associated diarrhea is causing uncontrolled bowel movements.

(iv) A toilet-trained person shall be readmitted when they regain control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day.

28. ***Shigellosis.***

(i) A person with shigellosis shall be excluded from child care group settings until the etiological organism has been eradicated, as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or a culture-independent diagnostic test. If antibacterial treatment has been given, the specimens may not be collected until 48 hours after the last dose of treatment was taken.

(ii) A person who is a household contact of an individual with shigellosis shall be excluded from attending, working or volunteering at child care group settings until the contact has obtained two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or a culture-independent diagnostic test. If the contact received antibacterial treatment, the specimens may not be collected until 48 hours after the last dose of treatment was taken.

		(iii) A toilet-trained person shall be excluded from school settings if the person's *Shigella*-associated diarrhea is causing uncontrolled bowel movements.
		(iv) A toilet-trained person shall be readmitted when the person regains control of bowel movements and when stool frequency is no more than two stools above normal for that person during the program day.
29.	***Shingles.***	**Exclusion of a person with shingles is not necessary, unless otherwise directed by a health care practitioner acting within the scope of their practice, so long as the rash is covered with clothing or a clean, dry bandage to prevent others and objects from coming into contact with the rash. If the rash cannot be covered the person shall be readmitted once all blisters have dried and crusted.**
30.	***Streptococcal respiratory infection (including strep throat and scarlet fever).***	**A person with a streptococcal respiratory infection shall be excluded from school and child care group settings until they have completed 12 hours of antibiotic treatment as prescribed by a health care practitioner acting within the scope of their practice.**

31.	***Tinea (ringworm).***	**Exclusion of a person with ringworm is not necessary before the end of the program day if the person's lesions are covered. The person shall be readmitted once treatment has begun so long as all lesions are covered until dry. Additionally, athletes in sports with person-to-person contact and active ringworm infections of the body may not participate in sports matches for 72 hours after starting treatment, unless the infected area can be covered.**
32.	***Tuberculosis.***	**A person with tuberculosis shall be excluded from school and child care group settings until the completion of two weeks of adequate chemotherapy or the treating health care practitioner provides a note stating that the person's disease is noncommunicable. Additionally, a person with tuberculosis is subject to the special requirements for tuberculosis under § 27.161 (relating to special requirements for tuberculosis).**

33.	***Typhoid fever or paratyphoid fever.***	**(i) A person with typhoid or paratyphoid fever shall be excluded from child care group settings until the etiological organism has been eradicated, as proven by three negative successive stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If antibacterial treatment or treatment with another chemotherapeutic drug effective against *Salmonella typhi* or *Salmonella paratyphi* was given, the specimens may not be collected until 48 hours after the last dose of treatment was taken. Specimens may not be collected earlier than 30 days after onset of symptoms.** **(ii) A person who is a chronic carrier of typhoid or paratyphoid fever shall be excluded from child care group settings until the etiologic organism has been eradicated, as proven by three consecutive negative stool specimens collected at least 30 days apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If the carrier received antibacterial treatment or treatment with another chemotherapeutic drug effective against**

Salmonella typhi **or** ***Salmonella paratyphi*****, the specimens may not be collected until 48 hours after the last does of treatment was taken.**

(iii) A person who is a household contact of an individual with typhoid or paratyphoid fever shall be excluded from attending, working or volunteering at a child care group setting until the contact has obtained two consecutive negative stool samples collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If the contact received antibacterial treatment or treatment with another chemotherapeutic drug effective against ***Salmonella typhi*** **or** ***Salmonella Paratyphi*****, the specimens may not be collected until 48 hours after the last dose of treatment was taken and if symptomatic, be collected no earlier than 30 days after onset of symptoms.**

34. ***Varicella (chickenpox).*** **(i) A person with varicella (chickenpox) shall be excluded from school and child care group settings until all lesions have dried and crusted, and no new red bumps or lesions have appeared for at least 24 hours.**

(ii) The Department may, in the course of conducting disease control measures under Subchapter C, exclude a person susceptible for varicella (chickenpox) from a school or child care group setting until the person provides proof that the person is not susceptible, receives a vaccine for varicella, or when no cases of varicella have occurred in the specific school or child care group setting for 21 days. A person susceptible for varicella includes a person who: presents no history of an age-appropriate dose of varicella vaccination while 12 months of age or older; does not have a diagnosis of varicella disease as set forth in a written record from a health care practitioner acting within the scope of their practice; does not demonstrate serological evidence of varicella immunity (the presence of antibodies to varicella determined by an enzyme-linked immunosorbent assay test or comparable test); and was born in the United States before 1980.

(b) A person who supervises food handlers or health care practitioners who provide direct care shall adhere to the following requirements for persons suspected or confirmed by a health care practitioner acting within the scope of their practice to have the specified disease, infection or condition, and for close contacts of such persons:

	Disease, infection or condition	***Requirements***
1.	***Amebiasis.***	**(i) A person with amebiasis may not work or volunteer as a health care practitioner or food handler until the etiologic organism has been eradicated, as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as an ova and parasite exam. If antiparasitic treatment has been given, the specimens may not be collected until 48 hours after the last dose of treatment was taken.** **(ii) A person who is a household contact of an individual with amebiasis may not work or volunteer as a food handler or health care practitioner until the contact has obtained two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department. If the contact received antiparasitic treatment, the specimens may not be collected until 48 hours after the last dose of treatment was taken.**

2.	***Hepatitis A and E or jaundice without a known etiology.***	**A person with hepatitis A, hepatitis E or jaundice without a known etiology may not work or volunteer as a health care practitioner or food handler until 1 week after the onset of jaundice. If the person does not present with jaundice, the person shall be allowed to resume working or volunteering once IgM antibody positivity is verified by a health care practitioner acting within the scope of their practice, or after 2 weeks have passed since symptom onset.**
3.	**Shiga toxin-producing *Escherichia coli* (*i.e.*, STEC).**	**(i) A person with a STEC infection may not work or volunteer as a health care practitioner or food handler until the etiologic organism has been eradicated, as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or by a culture-independent diagnostic test. If antibacterial treatment has been given, the specimens may not be collected until 48 hours after the last dose of treatment was taken.**

(ii) A person who is a household contact of an individual with a STEC infection may not work or volunteer as a food handler or health care practitioner until the contact has obtained two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as culture or a culture-independent diagnostic test. If the contact received antibacterial treatment, the specimens may not be collected until 48 hours after the last dose of treatment was taken.

4. ***Shigellosis.*** **(i) A person with shigellosis may not work or volunteer as a health care practitioner or food handler until the etiologic organism has been eradicated, as proven by two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or a culture-independent diagnostic test. If antibacterial treatment has been given, the specimens may not be collected until 48 hours after the last does of treatment was taken.**

		(ii) A person who is a household contact of an individual with shigellosis may not work or volunteer as a food handler or health care practitioner until the contact has obtained two consecutive negative stool specimens collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture or a culture-independent diagnostic test. If the contact received antibacterial treatment, the specimen may not be collected until 48 hours after the last dose of treatment was taken.
5.	***Streptococcal respiratory infection (including strep throat).***	**A person with a streptococcal infection may not work or volunteer as a health care practitioner or food handler until they have completed 12 hours of antibiotic treatment as prescribed by a health care practitioner acting within the scope of their practice.**
6.	***Typhoid fever or paratyphoid fever.***	**(i) A person with typhoid or paratyphoid fever may not work or volunteer as a health care practitioner or food handler until the etiologic organism has been eradicated, as proven by three negative successive stool specimens collected at intervals of at least 24 hours, as**

verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If antibacterial treatment or treatment with another chemotherapeutic drug effective against *Salmonella typhi* or *Salmonella Paratyphi* was given, the specimens may not be collected until 48 hours after the last dose of treatment was taken. Specimens may not be collected earlier than 30 days after onset of symptoms.

(ii) A person who is a chronic carrier of typhoid or paratyphoid fever may not work or volunteer as a health care practitioner or food handler until the etiologic organism has been eradicated, as proven by three consecutive negative stool specimens collected at least 30 days apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If the carrier received antibacterial treatment or treatment with another chemotherapeutic drug effective against *Salmonella typhi* or *Salmonella Paratyphi*, the specimens may not be collected until 48 hours after the last dose of treatment was taken.

(iii) A person who is a household contact of an individual with typhoid or paratyphoid fever may not work or volunteer as a food handler or health care practitioner until the contact has obtained two consecutive negative stool samples collected at least 24 hours apart, as verified by an appropriate clinical laboratory, by a test deemed acceptable to the Department, such as a culture test. If the contact received antibacterial treatment or treatment with another chemotherapeutic drug effective against *Salmonella typhi* or *Salmonella paratyphi*, the specimens may not be collected until 48 hours after the last dose of treatment was taken and if symptomatic, be collected no earlier than 30 days after onset of symptoms.

§ 27.72. Exclusion of children, students, [and] staff and other persons having direct contact with children and students, for showing symptoms.

(a) **[A person in charge of a public, private, parochial, Sunday or other school or college shall, following consultation with a physician or school nurse, exclude immediately a child, or staff person, including a volunteer, having contact with children, showing any of the following symptoms, unless that person is determined by the school nurse, or a physician, to be noncommunicable] A person in charge of a school, college, university or child care**

group setting shall exclude a person showing any of the following symptoms until a health care practitioner acting within the scope of their practice determines that the symptom is not due to an infectious cause:

(1) Mouth sores associated with inability to control saliva.

(2) Rash with fever or **rash with** behavioral change.

(3) Purulent discharge with fever or behavioral change **[from the eyes]**.

(4) Productive cough with fever.

(5) **[Oral or axillary temperature equal to or greater than 102° F.]** **A rectal, ear or forehead temperature of 100.4°F or higher; an oral or mouth temperature of 100°F or higher; or an under the arm temperature of 99°F or higher.**

(6) **[Unusual lethargy, irritability, persistent crying, difficulty breathing or other signs of severe illness.]** **Difficulty breathing suspected to be due to a communicable disease.**

(7) **[Persistent vomiting.]** **Refractory (resistant to treatment) vomiting or diarrhea.**

(8) **[Persistent diarrhea.]** **{Reserved}.**

(9) Draining wounds unless the wound is adequately covered.

(10) Diarrhea generally, unless due to a disease or condition requiring special measures, as specified in § 27.71a(a) (relating to exclusion and readmission of persons with specific diseases and infectious conditions who work or volunteer as food handlers or health care practitioners, students in schools, colleges or universities, children in child care group settings, and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting).

(11) Other signs of severe illness or known exposure to a communicable disease.

(b) The school**, college or university, or child care provider,** shall maintain a record of the exclusion and the reasons prompting the exclusion and shall review the record to determine when unusual rates of absenteeism occur.

§ 27.73. [Readmission of excluded children, and staff having contact with children.

(a) A child or staff person, including a volunteer, having contact with children, excluded from a public, private, parochial or other school or college under § 27.72 (relating to exclusion of children, and staff having contact with children, for showing symptoms) may not be readmitted until the school nurse or, in the absence of a school nurse, a physician, is satisfied that the condition for which the person was excluded is not communicable or until the person presents a statement from a physician that the person has recovered or is noninfectious.

(b) A child, or staff person, including a volunteer, having contact with children, excluded for the following reasons shall be readmitted only when a physician has determined the illness to be either resolved, noncommunicable or in a noncommunicable stage:

(1) Rash with fever or behavioral change.

(2) Productive cough with fever.] {Reserved}.

§ 27.74. Readmission of [exposed or isolated children, and staff having contact with children] students in a school, college or university, children in a child care group setting and persons having direct contact with students in a school, college or university or children in a child care group setting who are in isolation or quarantine.

[A child, or staff person, including a volunteer, having contact with children, who has been absent from school by reason of having had or because of residing on premises where there has been a disease for which isolation is required, may not be readmitted to school without

the permission of the LMRO.] **A person directed by the Department or local health department to be in isolation or quarantine shall only be readmitted to a school, college or university, or child care group setting, with the permission of the Department or local health department.**

§ 27.75. [Exclusion of children, and staff having contact with children, during a measles outbreak.

Children, and staff, including a volunteer, having contact with children, shall be excluded from school during a measles outbreak under the procedures described in § 27.160 (relating to special requirements for measles).] **{Reserved}.**

§ 27.76. [Exclusion and readmission of children, and staff having contact with children, in child care group settings.

(a) Sections 27.71—27.75 apply to child care group settings, with the exception that readmission of excluded persons as provided in those sections, as well as provided in this subsection, shall be contingent upon a physician verifying that the criteria for readmission have been satisfied. The following conditions and circumstances also govern exclusion from and readmission to a child care group setting of a child, or a staff person, including a volunteer, who has contact with children attending the child care group setting:

(1) ***Meningococcal meningitis or meningococcemia.*** **Until made noninfective by a course of rifampin or other drug which is effective against the nasopharyngeal carriage stage of this disease, or otherwise shown to be noninfective.**

(2) ***Haemophilus influenzae (H. flu) meningitis or other invasive H. flu disease.*** **Until made noninfectious by a course of rifampin or other drug which is effective against the nasopharyngeal carriage stage of this disease, or otherwise shown to be noninfective.**

(3) ***Persistent diarrhea.*** **Until resolved or judged to be noninfective when associated with any of the following:**

(i) Inability to prevent contamination of the environment with feces.

(ii) Fever.

(iii) Identified bacterial or parasitic pathogen.

(4) ***Fever in children younger than 4 months of greater than 101° F. rectally or 100° F. axillary; in children 4-24 months of greater than 102° F. rectally or 101° F. axillary.*** **Until resolved or judged to be noninfective.**

(5) ***Hepatitis A, viral hepatitis unspecified, or jaundice of unspecified etiology.*** **Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present.**

(6) ***Shigellosis.*** **Until the etiologic organism is eradicated. See § 27.158 (relating to special requirements for shigellosis).**

(7) ***Typhoid fever or paratyphoid fever.*** **Until the etiologic organism is eradicated. See § 27.159 (relating to special requirements for typhoid and paratyphoid fever).**

(8) ***Exposure to an individual with meningococcal disease.*** **Until the institution of treatment with appropriate antibiotic to eradicate the nasopharyngeal carrier state, or until proven noninfectious with nasopharyngeal cultures, or until 30 days following the exposure. Exclusion shall be postponed, until the second day following notice that exclusion will be required, to give the individual sufficient time to arrange for institution of appropriate antibiotic treatment.**

(b) To facilitate the proper exclusion of sick children and staff, the caregiver at a child care group setting shall arrange for the following:

(1) Instruction of staff, including volunteers, regarding exclusion and screening criteria that apply to themselves and attending children.

(2) Instruction of parents and guardians regarding exclusion criteria and that they are to notify the caregiver within 24 hours after it is determined or suspected that a child has an illness or condition for which exclusion is required.

(3) Follow up after exclusion of a child by staff at the time the child is brought to the child care group setting to ensure that the condition which required exclusion has been resolved.] **{Reserved}.**

§ 27.77. Immunization requirements for children in child care group settings.

(a) *Caregiver responsibilities.*

(1) Except as exempted in subsection (d), **[effective March 27, 2002,]** the caregiver at a child care group setting may not accept or retain a child 2 months of age or older at the setting, for more than 60 days, unless the caregiver has received a written objection to a child being vaccinated on religious grounds **or on the basis of a strong moral or ethical conviction similar to a religious belief** from a parent or guardian, or one of the following:

(i) For all children not exempt under subsection (d)(1)(ii), an initial written verification from a **[physician] health care practitioner acting within the scope of their practice**, the Department or a local health department of the dates (month, day and year) the child was administered **[any vaccines recommended by ACIP] each of the vaccines listed in subsection (b)**. The verification must also specify **[any] each** vaccination not given due to **a** medical condition of the child and state whether the condition is temporary or permanent. The verification must show compliance with the vaccination requirements in subsection (b).

(ii) For all children for whom vaccinations remain outstanding following the caregiver's receipt of the initial written verification, subsequent written verifications from a **[physician]** **health care practitioner acting within the scope of their practice**, the Department or a local health department **shall be submitted** as additional vaccinations become due. These **subsequent written** verifications shall be prepared in the same manner as set forth in subparagraph (i), but need not repeat information contained in a previously submitted verification. The **subsequent written** verifications must demonstrate continuing compliance with the vaccination requirements in subsection (b).

(2) If the caregiver receives a written verification under paragraph (1) explaining that timely vaccination did not occur due to a temporary medical condition, the caregiver shall exclude the child from the child care group setting after an additional 30 days unless the caregiver receives, within that 30-day period, written verification from a **[physician]** **health care practitioner acting within the scope of their practice**, the Department or a local health department that the child was vaccinated or that the temporary medical condition still exists. If the caregiver receives a written verification that vaccination has not occurred because the temporary condition persists, the caregiver shall require the presentation of a new verification at 30-day intervals. If a verification is not received as required, the caregiver shall exclude the child from the child care group setting and not readmit the child until the caregiver receives a verification that meets the requirements of this section.

(3) The caregiver shall retain the written verification or objection referenced in paragraphs (1) and (2) for 60 days following the termination of the child's attendance.

(4) The caregiver shall ensure that a certificate of immunization is completed and signed for each child enrolled in the child care group setting. The certificates shall be updated by the

caregiver to include the information provided to the caregiver under subsection (a) when that additional information is received. **[The immunization status of each enrolled child shall be summarized and reported on an annual basis to the Department at the time prescribed by the Department and on the form provided by the Department.]** **Upon request, the caregiver shall provide the Department with the immunization status of each enrolled child. The Department may review the immunization status of a child at the caregiver's location and may provide the caregiver with on-site immunization education.**

(b) **[*Vaccination*]** ***Immunity*** *requirements*. Each child enrolled in a child care group setting shall be immunized **[in accordance with ACIP standards in effect on January 1, 1999, governing the issuance of ACIP recommendations for the immunization of children.]** **against the following diseases as set forth below, verified by a health care practitioner acting within their scope of practice:**

(1) **[The standards are as follows:**

(i) The immunization practice is supported by both published and unpublished scientific literature as a means to address the morbidity and mortality of the disease.

(ii) The labeling and packaging inserts for the immunizing agent are considered.

(iii) The immunizing agent is safe and effective.

(iv) The schedule for use of the immunizing agent is administratively feasible.] **{Reserved}.**

(2) **[The Department will deem an ACIP recommendation pertaining to the immunization of children to satisfy the standards in this subsection unless ACIP alters its standards for recommending immunizations for children by eliminating a standard set forth in this subsection and the recommendation is issued under those changed standards.]** **{Reserved}.**

(3) Diphtheria, by age 6.

(4) Haemophilus *influenzae* type b, by 4 months of age.

(5) Hepatitis A, by 18 months of age.

(6) Hepatitis B, by 18 months of age.

(7) Measles, by age 6.

(8) Mumps, by age 6.

(9) Pertussis, by age 6.

(10) Pneumococcal disease, by 15 months of age.

(11) Poliovirus, by age 6.

(12) Rotavirus, by 6 months of age.

(13) Rubella, by age 6.

(14) Tetanus, by age 6.

(15) Varicella (chickenpox), by 15 months of age.

(b.1) For the purposes of this section, "immunized" means that a person is protected against a disease through multi-dose vaccination at appropriate intervals or natural immunity to the extent that a health care practitioner determines the person to have sufficient levels of antibodies to be exposed to the disease without becoming infected.

(c) **[*Notice*. The Department will place a notice in the *Pennsylvania Bulletin* listing publications containing ACIP recommendations issued under the standards in subsection (b). The Department published the initial notice at 32 Pa.B. 539 (January 26, 2002), contemporaneously with the adoption of amendments to this chapter. The Department will update that list in a notice which it will publish in the *Pennsylvania Bulletin* within 30 days after ACIP issues a recommendation which satisfies the criteria of this section.] {Reserved}.**

(d) *Exemptions*.

(1) This section does not apply to the following:

(i) Children attending kindergarten, elementary school or higher school who are 5 years of age or older. These caregivers shall comply with §§ 23.81—23.87 (relating to immunization).

(ii) A caregiver who does not serve as a caregiver for at least 40 hours during at least 1 month.

(2) The requirement imposed by subsection (a), to not accept a child into a child care group setting without receiving an initial written verification or objection specified in subsection (a), does not apply during a month the caregiver does not serve as a caregiver for at least 40 hours.

(e) *Exclusion when disease is present*. Whenever one of the diseases in **[§ 27.76 (relating to exclusion and readmission of children, and staff having contact with children, in child care group settings)]** **§ 27.71a (relating to exclusion and readmission of persons with specific diseases and infectious conditions who work or volunteer as food handlers or health care practitioners, students in schools, colleges or universities, children in child care group settings, and persons who have direct contact with students in a school, college or university or direct contact with children in a child care group setting)** has been identified within a child care group setting, the Department or a local health department may order the exclusion from the child care group setting or any other child care group setting which is determined to be at high-risk of transmission of that disease, of an individual susceptible to that disease in accordance with public health standards as determined by the Department.

Subchapter D. SEXUALLY TRANSMITTED DISEASES,TUBERCULOSIS AND OTHER COMMUNICABLE DISEASES

§ 27.81. Examination of persons suspected of being infected.

Whenever the Department or a local health authority has reasonable grounds to suspect a person of being infected with an organism causing a sexually transmitted disease, tuberculosis or other communicable disease, or of being a carrier, but lacks confirmatory medical or laboratory evidence, the Department or the local health authority may require the person to undergo a medical examination and any other approved diagnostic procedure to determine whether or not the person is infected or is a carrier. If the local health authority involved is not **[an LMRO]** **a local health department**, the local health authority shall consult with and receive approval from the Department prior to requiring any medical examination or other approved diagnostic procedure.

* * * * *

§ 27.83. Court ordered examinations.

The examination ordered by the court under § 27.82 (relating to refusal to submit to examination) may be performed by a physician chosen by the person at the person's own expense. The examination shall include an appropriate physical examination and laboratory tests performed in a clinical laboratory approved by the Department to conduct the tests, and shall be conducted in accordance with accepted professional practices. The results shall be reported to the **[local health authority or the Department on case report forms furnished by the Department]** **Department's electronic disease surveillance system**.

§ 27.84. Examination for a sexually transmitted disease of persons detained by police authorities.

* * * * *

(b) A person convicted of a crime or pending trial, who is confined in or committed to a State or local penal institution**[, reformatory]** or other house of correction or detention, may be

examined for a sexually transmitted disease by a qualified physician appointed by the Department or by the local health authority. If the person refuses to permit an examination or provide a specimen for laboratory tests as requested by the physician, judicial action may be pursued by the Department or local health authority to secure an appropriate remedy.

* * * * *

§ 27.85. [Diagnosis] Confidential diagnosis and treatment of a sexually transmitted disease.

(a) The Department will provide or designate adequate facilities for the free **confidential** diagnosis and, where necessary for the preservation of public health, free **confidential** treatment of persons infected with sexually transmitted diseases.

(b) Upon approval of the Department, a local health authority shall undertake to share the expense of furnishing free **confidential** diagnosis and free **confidential** treatment of a sexually transmitted disease, or shall furnish free **confidential** diagnosis and free **confidential** treatment of the sexually transmitted disease without financial assistance from the Department.

§ 27.87. Refusal to submit to treatment for communicable diseases.

(a) If the Department or a local health authority finds that a person who is infected with a sexually transmitted disease, tuberculosis or other communicable disease in a communicable stage refuses to submit to treatment approved by the Department or by a local health authority, the Department or the local health authority, if it determines the action advances public health interests, shall order the person to be isolated in an appropriate institution designated by the Department or by the local health authority for safekeeping and treatment until the disease has been rendered noncommunicable.

* * * * *

(ii) If the local health authority involved is not **[an LMRO]** **local health department**, the local health authority shall consult with and receive approval from the Department prior to taking any action under this subsection.

* * * * *

(c) **[For the purpose of this section, treatment approved by the Department or by a local health authority may include treatment by an accredited practitioner of a well recognized church or religious denomination which relies on prayer or spiritual means alone for healing, if requirements relating to sanitation, isolation or quarantine are satisfied.]** **{Reserved}.**

* * * * *

§ 27.89. Examinations for syphilis.

(a) *Prenatal examination for syphilis.*

(1) *Blood sample.*

(i) A **[physician who]** **health care practitioner who within the scope of their practice** attends, treats or examines a pregnant **[woman]** **individual** for conditions relating to pregnancy during the period of gestation or delivery shall inform the **[woman]** **individual** that **[he]** **the practitioner** intends to take or cause to be taken, unless the **[woman]** **individual** objects, a sample of **[her]** blood at the time of the first examination (including the initial visit when a pregnancy test is positive), or within 15 days after the first examination, and shall submit the sample to a clinical laboratory for an approved test for syphilis.

(ii) **[A physician shall similarly collect and have tested a sample of the pregnant woman's blood during the third trimester of her pregnancy, in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring**

in a given population for which the CDC has determined it is cost-effective to require special precautions.] **A health care practitioner who within the scope of their practice attends, treats or examines a pregnant individual for conditions relating to pregnancy during the third trimester of pregnancy shall inform the individual that the practitioner intends to take or cause to be taken, unless the individual objects, a sample of blood and shall submit the sample to a clinical laboratory for an approved test for syphilis.**

(iii) **[The Department will publish the list of those counties in which this rate is occurring in the *Pennsylvania Bulletin* as necessary.]** **{Reserved}.**

(iv) Other persons permitted by law to attend pregnant **[women]** **individuals**, but not permitted by law to take blood samples, shall, unless the **[woman]** **individual** objects, cause a blood sample to be taken and submitted to a clinical laboratory for an approved test for syphilis.

(v) If the pregnant **[woman]** **individual** objects, it shall be the duty of the person attending the pregnant **[woman]** **individual** and seeking to have the **[woman]** **individual** give a blood sample to explain to **[her]** **the individual** the desirability of the test.

(2) *Charge for test.* The serological test required by paragraph (1) will be made without charge, facilitated by the Department, upon the request of the **[physician]** **health care practitioner** submitting the blood sample and **[the submission of a certificate by the physician that]** **if** the patient is unable to pay.

(b) *Examination for syphilis in* ***[mother of newborn]*** ***postpartum individuals***. A test for syphilis shall be done, unless the **[mother]** **postpartum individual** objects, on the blood of the **[mother]** **postpartum individual** of every newborn delivered **[in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given**

population for which the CDC has determined it is cost-effective to require special precautions].

(1) **[The Department will publish the list of counties in which this rate is occurring in the *Pennsylvania Bulletin* as necessary.]** **{Reserved}.**

(2) The results of the test shall be recorded both in the **[mother's]** **postpartum individual's** medical record and in the newborn's medical record prior to discharge.

(c) *Examination for syphilis in* ***[mother of stillborn]*** ***case of stillbirth***.

(i) A test for syphilis shall be done, unless the **[mother]** **postpartum individual** objects, on the blood of the **[mother]** **postpartum individual** of every stillborn child **[delivered in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions]**.

(ii) **[The Department will publish the list of counties in which this rate is occurring in the *Pennsylvania Bulletin* as necessary.]** **{Reserved}.**

(iii) **[The Department will be responsible for alerting physicians about this standard.]** **{Reserved}.**

(iv) The blood shall be collected within 2 hours after delivery and the result entered into the **[mother's]** **postpartum individual's** medical record prior to discharge. See also, § 27.95 (relating to reporting syphilis examination information for births and fetal deaths).

§ 27.95. Reporting syphilis examination information for births and fetal deaths.

In reporting a birth or fetal death, **[physicians and others required to make the reports]** **health care practitioners** shall state in the medical record whether or not the blood tests required by § 27.89(b) (relating to examinations for syphilis) were made. If a test was made, the

date of the test shall be given, and if a test was not made, the reason the test was not made shall be given.

§ 27.96. Diagnostic tests for sexually transmitted diseases.

(a) When testing for a sexually transmitted disease is required by the act or this chapter, the test used shall be a test approved by the **[Food and Drug Administration]** **FDA**, and if a laboratory test is part of the approved procedure, it shall be conducted in a clinical laboratory approved by the Department to perform the test.

(b) The diagnostic tests that have been approved to test for each sexually transmitted disease may be ascertained by contacting the **[Division of Clinical Microbiology,]** **Department's** Bureau of Laboratories.

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§ 27.98. Prophylactic treatment of newborns.

(a) **[Physicians and midwives attending women]** **A health care practitioner acting within the scope of their practice who attends individuals** in childbirth shall instill in each eye of the newborn child, as soon as practicable after birth, either a 1% silver nitrate solution, or erythromycin ophthalmic ointment or solution as a single application in both conjunctival sacs, or **other** appropriate medication approved by the Department.

(b) If the parent or guardian of the newborn child objects on the ground that the prophylactic treatment conflicts with the parent's or guardian's religious beliefs or practices, or if in the opinion of the attending **[physician]** **health care practitioner** treatment is not advisable, prophylactic treatment shall be withheld.

(c) An entry in the child's hospital record indicating the reason for withholding treatment shall be made and signed by the attending **[physician]** **health care practitioner** and the parent or guardian.

§ 27.99. Prenatal examination for hepatitis B.

(a) A **[physician]** **health care practitioner acting within the scope of their practice** who attends, treats or examines a pregnant **[woman]** **individual** for conditions relating to pregnancy during the period of gestation or delivery, shall inform the **[woman]** **individual** that the **[physician]** **health care practitioner** intends to take or cause to be taken, unless the **[woman]** **individual** objects, a sample of **[her]** blood at the time of the first examination (including the initial visit when a pregnancy test is positive) or within 15 days thereafter, but no later than the time of delivery, and shall submit the sample to a **[clinical laboratory approved by the Department to conduct immunologic testing]** **laboratory authorized to conduct testing for hepatitis B under applicable State and Federal law**.

(b) When a pregnant **[woman]** **individual** tests positive for hepatitis B surface antigen, **[a physician]** **the health care practitioner acting within the scope of their practice** shall provide the appropriate prophylactic treatment to the newborn within 12 hours after birth. If the parent or guardian of the newborn child objects on the ground that the prophylactic treatment conflicts with the parent's or guardian's religious beliefs or practices, prophylactic treatment shall be withheld, and an entry in the child's hospital record indicating the reason for withholding treatment shall be made and signed by the attending physician and the parent or guardian.

§ 27.99a. Prenatal examination for hepatitis C.

(a) A health care practitioner acting within the scope of their practice who attends, treats or examines a pregnant individual for conditions relating to pregnancy during the period

of gestation or delivery, shall inform the individual that the health care practitioner intends to take or cause to be taken, unless the individual objects, a sample of blood at the time of the first examination (including the initial visit when a pregnancy test is positive) or within 15 days thereafter, but no later than the time of delivery, and shall submit the sample to a laboratory authorized to conduct testing for hepatitis C under applicable State and Federal law.

(b) When a pregnant individual tests positive for hepatitis C ribonucleic acid, the health care practitioner acting within the scope of their practice shall refer the birthing individual and the infant to appropriate follow up care.

§ 27.99b. Prenatal examination for HIV.

A health care practitioner acting within the scope of their practice who attends, treats or examines a pregnant individual for conditions relating to pregnancy during the period of gestation or delivery, shall inform the individual that the health care practitioner intends to take or cause to be taken, unless the individual objects, a sample of blood at the time of the first examination (including the initial visit when a pregnancy test is positive) or within the first trimester and the third trimester but no later than the time of delivery, and shall submit the sample to a laboratory authorized to conduct testing for HIV under applicable State and Federal law.

Subchapter E. SELECTED PROCEDURES FOR PREVENTING DISEASE TRANSMISSION

§ 27.151. [Restrictions on the donation of blood, blood products, tissue, sperm and ova.

(a) A person known to be, or suspected of being, infected with the causative agent of a reportable disease is not allowed to donate blood, blood products, tissue, sperm or ova for use in other human beings.

(1) In addition, a person or entity may not accept any of these materials from a person known to be, or suspected of being, infected with the causative agent of a reportable disease for donation without obtaining laboratory evidence showing the absence of hepatitis B, hepatitis C, HIV or other diseases and infections, which the Department may specify by placing a notice in the *Pennsylvania Bulletin*.

(2) The list of additional diseases and conditions will not remain in effect for more than 90 days after publication unless the Board acts to affirm it within that 90-day period.

(b) The only exception to a person or entity accepting donations without obtaining laboratory evidence showing the absence of diseases and infections designated by the Department is when the delay that would be necessary to properly test the blood of the donor would threaten the recipient's survival.] **{Reserved}.**

§ 27.152. [Investigation of cases and outbreaks.

(a) The Department or a local health authority may investigate any case or outbreak of disease judged by the Department or local health authority to be a potential threat to the public health.

(b) A person may not interfere with or obstruct a representative of the Department or a local health authority who seeks to enter a house, health care facility, building or other premises to carry out an investigation of a case or outbreak, if the representative presents documentation to establish that he is an authorized representative of the Department or the local health authority.

(c) In the course of conducting an investigation of a case or outbreak, the authorized representative of the Department or local health authority may conduct a confidential review of medical records. A person may not interfere with or obstruct this review.]

{Reserved}.

§ 27.153. [Restrictions on food handlers.

A person with the following diseases or conditions may not work as a food handler, see, also, 3 Pa.C.S. Chapter 65 (relating to the Food Employee Certification Act) and 7 Pa. Code §§ 78.41—78.43 (Reserved), except as follows:

(1) *Amebiasis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antiparasitic treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.156 (relating to the special requirements for amebiasis).

(2) *Enterohemorrhagic E. coli.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.157 (relating to the special requirements for enterohemorrhagic E. coli).

(3) *Shigellosis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.158 (relating to the special requirements for shigellosis).

(4) ***Typhoid fever or paratyphoid fever.*** **Until the etiologic organism has been eradicated as proven by three negative successive stool specimens collected at intervals of at least 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. See § 27.159 (relating to the special requirements for typhoid and paratyphoid fever).**

(5) ***Hepatitis A, viral hepatitis, or jaundice of unspecified etiology.*** **Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician.**

(6) ***Persistent diarrhea.*** **Until resolved or judged to be noninfective by a physician.]**

{Reserved}.

§ 27.154. [Restrictions on caregivers in a child care group setting.

A person with the following diseases or conditions may not work as a care giver in a child care group setting if the caregiver attends or works in a capacity which requires direct contact with children except as follows:

(1) ***Amebiasis.*** **Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.156 (relating to the special requirements for amebiasis).**

(2) ***Enterohemorrhagic E. coli.*** **Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected**

sooner than 48 hours after treatment was completed. See § 27.157 (relating to the special requirements for enterohemorrhagic E. coli).

(3) *Shigellosis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.158 (relating to the special requirements for shigellosis).

(4) *Typhoid fever or paratyphoid fever.* Until the etiologic organism is eradicated as proven by three negative successive stool specimens collected at intervals of no less than 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. See § 27.159 (relating to the special requirements for typhoid and paratyphoid fever).

(5) *Hepatitis A, viral hepatitis or jaundice of unspecified etiology.* Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician.

(6) *Persistent diarrhea.* Until resolved or judged to be noninfective by a physician.]

{Reserved}.

§ 27.155. [Restrictions on health care practitioners.

Persons with the following diseases or conditions may not work as health care practitioners who provide direct patient care:

(1) *Amebiasis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antiparasitic treatment has been given, the specimens may not be collected sooner than 48

hours after treatment was completed. See § 27.156 (relating to the special requirements for amebiasis).

(2) ***Enterohemorrhagic E. coli.*** **Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.157 (relating to the special requirements for enterohemorrhagic E. coli).**

(3) ***Shigellosis.*** **Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.158 (relating to the special requirements for shigellosis).**

(4) ***Typhoid fever or paratyphoid fever.*** **Until the etiologic organism is eradicated as proven by three negative successive stool specimens collected at intervals of no less than 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. See § 27.159 (relating to the special requirements for typhoid or paratyphoid fever).**

(5) ***Hepatitis A, viral hepatitis or jaundice of unspecified etiology.*** **Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician.**

(6) ***Persistent diarrhea.*** **Until resolved or judged to be noninfective by a physician.]**

{Reserved}.

§ 27.156. [Special requirements for amebiasis.

A household contact of a case of amebiasis who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antiparasitic therapy, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Entamoeba histolytica.] {Reserved}.

§ 27.157. [Special requirements for enterohemorrhagic E. coli.

A household contact of a case of enterohemorrhagic E. coli, who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antimicrobial therapy, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for enterohemorrhagic E. coli.] {Reserved}.

§ 27.158. [Special requirements for shigellosis.

A household contact of a case of shigellosis, who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antimicrobial therapy, to an appropriate clinical laboratory for bacteriologic examination and the specimens are determined by the laboratory to be negative for shigella.] {Reserved}.

§ 27.159. [Special requirements for typhoid and paratyphoid fever.

(a) An asymptomatic household contact of a case of typhoid fever or paratyphoid fever who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two stool specimens, taken at least 24 hours apart, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Salmonella typhi or Salmonella paratyphi.

(b) A symptomatic household contact of a case of typhoid or paratyphoid fever who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which involves contact with children, or who provides direct patient care shall be required to cease work until bacteriologic examination of three consecutive stool specimens, taken at least 24 hours apart and no sooner than 48 hours after any microbial therapy, and no earlier than 1 month after onset, are reported as negative.

(c) A chronic carrier of typhoid or paratyphoid fever shall be excluded from preparing or serving food for public consumption, attending or working in a child care group setting in a capacity which involves contact with children, and providing direct patient care, until three consecutive negative fecal cultures are obtained from specimens taken at least 1 month apart and at least 48 hours after antibiotic therapy has stopped.] **{Reserved}.**

§ 27.160. [Special requirements for measles.

(a) ***Isolation.*** **An infected person shall be restricted to the premises for 4 days after the appearance of the rash.**

(b) *Quarantine.* Whenever measles is determined to be present in a school or child care group setting population, the Department or a local health department may do the following:

(1) Ascertain which children and staff persons are presumed susceptibles. A presumed susceptible is a person who fits into all of the following categories:

(i) Presents no history of two doses of measles vaccination, separated by at least 1 month, while 12 months of age or older.

(ii) Does not demonstrate serological evidence of measles immunity. The serological evidence is the presence of antibody to measles determined by the hemagglutination inhibition test or a comparable test.

(iii) Was born after December 31, 1956.

(2) Order exclusion from the school or child care group setting of presumed susceptible children and staff persons who do not present evidence of having received measles vaccination within 30 days prior to the outbreak. Exclusion shall continue until the excluded persons prove they do not meet the exclusion criteria in paragraph (1), they receive a measles vaccination, or no case of measles has occurred for a 14-day period.]

{Reserved}.

§ 27.161. Special requirements for tuberculosis.

(a) *Isolation.* A person suspected of having tuberculosis in its communicable stage shall be isolated in the following manner:

(1) Isolation for tuberculosis shall be established at the usual residence of the person suffering from tuberculosis whenever facilities for adequate isolation of the infectious person are available at the residence, if the person will accept the isolation. Isolation of a person treated at a

residence shall include instruction in the need to cover the mouth and nose when coughing and sneezing, and careful handling and disposal of sputum.

(2) If isolation for tuberculosis cannot be accomplished or maintained at the usual residence of the person and whenever, in the opinion of the Department or local health authority, the person is a health threat to others, by reason of the person's habits, neglect of treatment or noncompliance with the measures designed to protect others from infection, the isolation shall be enforced by following the procedures in § 27.87 (relating to refusal to submit to treatment for communicable diseases).

(i) Isolation of a person treated in an appropriate institution shall be in accordance with *CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* [**and any updates thereto as approved by the Board]** **as published in the *Morbidity and Mortality Weekly Report* (December 30, 2005)**.

(ii) [**The Department will publish notice in the *Pennsylvania Bulletin* of updates of this publication within 30 days after Board approval is obtained.]** **{Reserved}.**

(b) *Handling of contacts.* A human household contact or other close human contact shall be required to have a **[Mantoux tuberculin test]** **tuberculosis screening test** or chest X-ray, or both. A close human contact means a person who spends a substantial amount of time with a person who has infectious tuberculosis. If the person refuses, enforcement shall be accomplished as designated in §§ 27.82 and 27.83 (relating to request to submit to examination; and court ordered examinations). If evidence of tuberculosis in contacts is found on chest X-rays or by symptoms, laboratory studies shall be conducted to determine if the contacts represent a public health threat.

(c) *DOT*. A person with a suspected or confirmed case of tuberculosis shall be provided DOT until the person's course of treatment for suspected or confirmed tuberculosis is complete. A health care practitioner or health care provider shall notify the Department or local health department if DOT is provided to a person and record all DOT visits. A health care practitioner or health care provider shall provide records of DOT to the Department or local health department, upon request.

§ 27.162. Special requirements for animal bites, scratches or contamination of open wounds or mucous membranes.

Except as may be otherwise required by the Dog Law (3 P.S. §§ 459-101—459-1205) and regulations promulgated by the Department of Agriculture in 7 Pa. Code Chapters 21, 23, 25 and 27, quarantine of **[a biting animal]** **an animal that has potentially exposed a human to rabies through a bite, scratch or contamination of an open wound or mucous membrane** shall conform to the following:

(1) When an animal bites or otherwise potentially exposes a human to rabies, the Department or local health authority shall, after the case of an animal bite is reported, determine whether the animal shall be immediately destroyed and its head submitted to one of the State or county diagnostic laboratories for a rabies examination or whether some other action shall be pursued.

(2) Notwithstanding paragraph (1), when a healthy dog**, [or]** cat **or ferret** bites or otherwise potentially exposes a human to rabies, the dog**, [or]** cat**, or ferret** shall be **[quarantined] confined** in a place and manner approved by the Department or the local health officer for 10 days after the date of the bite, unless the Department or local health officer directs otherwise.

(3) If **[a quarantine] confinement** is imposed, the Department or the local health officer may order the owner or custodian of a biting animal to have the animal examined for symptoms of

rabies during the **[quarantine]** **confinement** period by a veterinarian licensed by the State Board of Veterinary Medicine. The cost of the examinations and other associated costs shall be borne by the owner or custodian of the biting animal.

§ 27.163. [Special requirements for psittacosis.

A quarantine is not required for household contacts of a bird that is a carrier of psittacosis. However, parts of any buildings that housed birds infected with psittacosis may not be used by human beings until thoroughly cleaned and disinfected.] **{Reserved}.**

§ 27.164. [Special requirements for close contacts of cases of plague, pharyngitis or pneumonia.

A close contact of any person or animal that is diagnosed as having plague (Yersinia pestis) pharyngitis, or pneumonia shall be provided chemoprophylaxis and placed under surveillance for 7 days.] **{Reserved}.**

Subchapter F. MISCELLANEOUS PROVISIONS

PSITTACOSIS

§ 27.181. [Records of the sale, purchase or exchange of psittacine birds.

A dealer who purchases, sells, exchanges or gives away a bird of the psittacine family shall keep a record for 2 years of each transaction. This record shall include the number of birds purchased, sold, exchanged or given away, the date of the transaction, and the name and address of the person from whom purchased, to whom sold or given away, or with whom exchanged. Records shall be available for official inspection.] **{Reserved}.**

§ 27.182. [Procurement of birds where psittacosis exists.

No person who sells, exchanges, gives away or otherwise disposes of psittacine birds may procure the birds from a source where psittacosis is known to exist.] **{Reserved}.**

§ 27.183. Occurrence of psittacosis.

(a) The occurrence of a case of psittacosis in **[the]** **a** human **[or avian family]** shall be cause for the **[LMRO]** **Department or local health department** to make an epidemiologic investigation to determine the source of infection.

(b) Psittacine birds or other birds found on the same premises with a case of human or avian psittacosis shall be **[quarantined]** **placed in quarantine** and treated, or destroyed, as prescribed by the Department or local health authority. Aviaries, pet shops or other sources from which the birds were procured shall be **[quarantined]** **placed in quarantine** until the quarantine is terminated by the Department or local health authority. If quarantine is not maintained, the Department or local health authority may seize and destroy the birds for which quarantine was ordered. The Department or local health authority shall destroy the bodies of the birds in a manner which will preclude, insofar as possible, the dissemination of the suspected infecting organism.

(c) **[A bird with psittacosis that has been placed under quarantine may not be sold or removed from isolation until it has been treated for at least 7 days. After 7 days, the bird may be sold, but the seller shall make the buyer aware in writing of the significance of psittacosis and the signs and symptoms for which to look. The signed receipt shall include a copy of any documents provided to the new owner, and shall be maintained at the place of sale for 6 months after the sale of the quarantined bird. The duration of additional treatment necessary shall be established at the time of sale and the seller shall inform the new owner of the duration of the additional treatment. The seller shall supply the new owner with a supply of medicated feed sufficient for the duration of the treatment.]** **{Reserved}.**

[IMPORTATION] RESTRICTION OF ANIMALS AND ANIMAL PRODUCTS AND MATERIALS

§ 27.191. [Importation] Restriction of animals and animal products and materials to prevent a public health emergency and during a public health emergency.

[In the event of a public health emergency, the Department may direct the following procedures for the importation of animals or animal products:

(1) *Permit required.* The Department may designate a specific type of animal or animal product which may not be brought or transported into this Commonwealth unless that animal or animal product is accompanied by a permit issued by the Department or other agency authorized by the Department to issue permits.

(2) *Issuance of permits.* A permit will be issued upon request if the source of the animal or animal product is established to the satisfaction of the Department or its agent and that source is known to be free of infection.

(3) *Destruction of animals and animal products.* If the animal or animal product is not accompanied by a permit or if the source is not the same as that set forth in the permit, the animal or animal product shall be immediately seized and destroyed and the means of conveyance disinfected at the expense of the owner.]

To prevent a public health emergency or during a public health emergency, the Department may restrict the movement of animals and animal products and materials suspected or known to be contaminated by a pathogen that poses a threat to human health. Animal products and animal-related materials include, but are not limited to, animal bedding, animal carcasses, animal feed, animal waste, equipment utilized for the care of animals, and food products made from animals.

§ 27.192. [Importation and sale of live turtles.

A live turtle may not be sold or distributed or offered for sale or distribution within this Commonwealth except when the seller or distributor of the turtles shall warrant to the satisfaction of the Department that the shipment of turtles is free from salmonella contamination. The Department may waive the requirements of this section for live turtles sold or distributed within this Commonwealth for the purposes of research, other zoological purposes or for food.] **{Reserved}.**

DISPOSITION OF EFFECTS AND REMAINS OF INFECTED PERSONS

§ 27.201. Disposition of articles exposed to contamination.

A person may not give, lend, sell, transmit or expose, without previous cleaning and a certificate from the Department or local health authority attesting to the cleaning of **[bedding, clothing, rags or other]** articles which have been exposed to contamination from **[bubonic plague, smallpox (variola, varioloid) or anthrax]** **a select agent or toxin**, except when the transmission of the articles is made with proper precaution and with the permission of the Department or local health authority for the purpose of having them cleaned.

§ 27.202. Lease of premises [occupied by a person with a communicable disease] exposed to a select agent or toxin.

A person may not rent a room, house or part of a house **[in which there has been a person suffering from a communicable disease]** **that has been exposed to contamination from a select agent or toxin** to another person without having the room, house or part of a house and articles therein previously cleaned to the satisfaction of the Department or local health authority prior to occupancy. The keeping of a hotel, boarding house or an apartment house shall be

deemed as renting part of a house to a person who shall be admitted as a guest into the hotel, boarding house or apartment house.

§ 27.203. Preparation for burial or transportation of deceased human bodies.

[In the preparation for burial of a body of a person who had died of amebiasis, anthrax, cholera, diphtheria, plague, poliomyelitis, scarlet fever, shigellosis, smallpox, typhoid fever, paratyphoid fever, salmonellosis or other known or suspected communicable diseases it shall be the duty of the undertaker or person acting as such to disinfect thoroughly by arterial and cavity injection with approved disinfectant fluid and to wash the surface of the body with an efficient germicidal solution and to effectually plug the body orifices.]

(a) Except as provided for in subsection (b), an undertaker or person acting as such shall do the following when preparing a person, who has died of a communicable disease, for burial:

(1) Disinfect the body by arterial and cavity injection with approved disinfectant fluid.

(2) Wash the surface of the body with an efficient germicidal solution.

(3) Plug the body orifices.

(b) The body of a person who died of smallpox or a viral hemorrhagic fever, including Ebola or Marburg, that can be transmitted in postmortem care settings through splashes of blood or other body fluids to unprotected mucosa during postmortem care, must only be handled as minimally necessary by a person in personal protective equipment and must not be washed, cleaned or embalmed. The burial method must be cremation, or if cremation is not possible, the body must be buried in a standard metal casket.

§ 27.204. Funeral services.

Services held **[in connection with the funeral]** **with the body** of a person who has died **[with a disease for which isolation or quarantine is required]** **of anthrax, Creutzfeldt-Jakob disease, invasive group A streptococcal infection, plague, rabies, smallpox, yellow fever, viral hemorrhagic fever, including Ebola or Marburg, viral hepatitis, or other known or suspected communicable disease associated with a public health emergency**, shall be private when so ordered by the Department or local health authority having jurisdiction in the area in which the services shall be held. When the local health authority is not **[an LMRO]** **a local health department**, the local health authority shall consult with and receive the approval of the Department prior to making the order. **[The]** **Unless the order of the Department or local health department states otherwise,** attendance at private funerals shall include only the immediate relatives of the deceased**, the officiating person** and the necessary number of pallbearers.

COMMONWEALTH OF PENNSYLVANIA
HEALTH

June 4, 2026

David Sumner, Executive Director
Independent Regulatory Review Commission
555 Walnut Street, Suite 804
Harrisburg, PA 17101

Re: Department of Health – Proposed Regulation No. 10-242
Communicable and Noncommunicable Diseases
28 Pa. Code Chapter 27

Dear Mr. Sumner:

Enclosed are proposed regulations for review by the Independent Regulatory Review Commission (IRRC) in accordance with the Regulatory Review Act (Act) (71 P.S. §§ 745.1—745.15).

The Department proposes to amend 28 Pa. Code Chapter 27 (relating to communicable and noncommunicable diseases) as comprehensive amendments are needed to expand the list of reportable diseases, infections and conditions, to address changing standards and recommendations from experts, such as the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP), and to ensure the overall public health and safety by reducing the risk and spread of diseases, infections and conditions.

The Department anticipates the proposed regulations to be published in the *Pennsylvania Bulletin* on August 8, 2026. A 45-day public comment period is provided. As required by section 5(c) of the Act, 71 P.S. § 745.5(c), the Department will provide to IRRC a copy of any comment received pertaining to the proposed regulations, within 5 business days of receipt. The Department will also provide IRRC with any assistance it requires to facilitate a thorough review of the proposed regulations.

Sincerely,

Debra L. Bogen MD

Debra L. Bogen, MD, FAAP
Secretary of Health

Enclosures

From: Burnett, David
To: Smith, Pamela (Health)
Cc: Brooks, Senator Michele
Subject: RE: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Date: Thursday, June 4, 2026 8:52:48 AM
Attachments: image001.png

Good morning Pam,

This email is to confirm receipt of the proposed regulations.

Regards,
-David

David Burnett
Counsel and Executive Director
Senate Health & Human Services Committee
Harrisburg, PA 17120

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Thursday, June 4, 2026 8:07 AM
To: Burnett, David <dburnett@pasen.gov>
Cc: Brooks, Senator Michele <mbrooks@pasen.gov>
Subject: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Importance: High

Good morning,

Attached is a proposed regulatory package from the Department of Heath for communicable and noncommunicable diseases (# 10-242).

The Regulatory Review Act requires delivery of the proposed regulatory package to the Standing Committees of the General Assembly, the Legislative Reference Bureau (LRB), and the Independent Regulatory Review Commission (IRRC) **on the same day**, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees and LRB is required for delivery to IRRC.

Please respond as soon as possible to this email indicating that you have received the attached proposed regulatory package so that I can deliver the package to IRRC **today, June 4, 2026**.

Best,

Pam

RECEIVED
Independent Regulatory
Review Commission
June 4, 2026

Pamela G. Smith
Assistant Chief Counsel

Department of Health | Office of Chief Counsel
625 Forster Street, 8th Floor | Harrisburg, PA 17120-0701
Phone: 717.783.2500
health.pa.gov

From: Fricke, Erika L.
To: Smith, Pamela (Health)
Cc: Frankel, Dan
Subject: RE: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Date: Thursday, June 4, 2026 9:22:23 AM
Attachments: image001.png

Received!

Erika Fricke
Democratic Executive Director / Pennsylvania House Health Committee
State Rep. Dan Frankel, Chair
Cell: 717-908-7023

Please email all scheduling requests to repfrankel@pahouse.net

---

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Thursday, June 4, 2026 8:08 AM
To: Fricke, Erika L. <EFricke@pahouse.net>
Cc: Frankel, Dan <DFrankel@pahouse.net>
Subject: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Importance: High

Good morning,

Attached is a proposed regulatory package from the Department of Heath for communicable and noncommunicable diseases (# 10-242).

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Best,
Pam

Pamela G. Smith
Assistant Chief Counsel

Department of Health | Office of Chief Counsel
625 Forster Street, 8th Floor | Harrisburg, PA 17120-0701
Phone: 717.783.2500
health.pa.gov

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Independent Regulatory Review Commission
June 4, 2026

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June 4, 2026

From: Freeman, Clarissa
To: Smith, Pamela (Health)
Cc: Haywood, Senator Art
Subject: RE: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Date: Thursday, June 4, 2026 9:20:21 AM
Attachments: image001.png

Received.

Clarissa L. Freeman
Deputy Chief Counsel | Senate Democratic Caucus
Executive Director-Health and Human Services Committee
717-783-1220

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Thursday, June 4, 2026 8:07 AM
To: Freeman, Clarissa <clarissa.freeman@pasenate.com>
Cc: Haywood, Senator Art <art.haywood@pasenate.com>
Subject: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Importance: High

■ EXTERNAL EMAIL ■

Good morning,

Attached is a proposed regulatory package from the Department of Heath for communicable and noncommunicable diseases (# 10-242).

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Please respond as soon as possible to this email indicating that you have received the attached proposed regulatory package so that I can deliver the package to IRRC **today, June 4, 2026**.

Best,
Pam

Pamela G. Smith
Assistant Chief Counsel

Department of Health | Office of Chief Counsel

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June 4, 2026

625 Forster Street, 8th Floor | Harrisburg, PA 17120-0701
Phone: 717.783.2500
health.pa.gov

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Review Commission

June 4, 2026

From: Bulletin
To: Smith, Pamela (Health)
Cc: Alyssa M. Burns; Adeline E. Gaydosh
Subject: [External] RE: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242) (LRB)
Date: Thursday, June 4, 2026 10:06:05 AM
Attachments: image001.png

Good morning,

Thank you for the official submission of this proposed rulemaking. As we discussed previously, it has been scheduled for publication in the August 8th issue of the *Pennsylvania Bulletin*.

Have a great day!

Alyssa Burns | Legal Assistant
aburns@palrb.us | 717.783.1531
Legislative Reference Bureau
Pennsylvania Code & Bulletin Office
647 Main Capitol Building
Harrisburg, PA 17120

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Thursday, June 4, 2026 9:24 AM
To: Bulletin <bulletin@palrb.us>
Subject: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242) (LRB)
Importance: High

Good morning,

Attached is a proposed regulatory package from the Department of Heath for communicable and noncommunicable diseases (# 10-242). The entire package is attached as a .pdf with Word versions of the Annex and Preamble.

The Regulatory Review Act requires delivery of the proposed regulatory package to the Standing Committees of the General Assembly, the Legislative Reference Bureau (LRB), and the Independent Regulatory Review Commission (IRRC) **on the same day**, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees and LRB is required for delivery to IRRC.

Please respond as soon as possible to this email indicating that you have received the attached

proposed regulatory package so that I can deliver the package to IRRC **today, June 4, 2026**.

Best,
Pam

Pamela G. Smith
Assistant Chief Counsel

Department of Health | Office of Chief Counsel
625 Forster Street, 8th Floor | Harrisburg, PA 17120-0701
Phone: 717.783.2500
health.pa.gov

From: Michael Siget
To: Smith, Pamela (Health)
Cc: Kathy Rapp
Subject: Re: [EXTERNAL]: Proposed Communicable and Noncommunicable Diseases Regulations (# 10-242)
Date: Thursday, June 4, 2026 8:50:33 AM
Attachments: image001.png

Received.
Thank you. Mike.

On Jun 4, 2026, at 8:08 AM, Smith, Pamela (Health) <pamesmith@pa.gov> wrote:

Good morning,

Attached is a proposed regulatory package from the Department of Heath for communicable and noncommunicable diseases (# 10-242).

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Best,
Pam

<image001.png>

Pamela G. Smith
Assistant Chief Counsel

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625 Forster Street, 8th Floor | Harrisburg, PA 17120-0701
Phone: 717.783.2500
health.pa.gov