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Independent Regulatory Review Commission

Senate of Pennsylvania

September 21, 2026

Chairman George D. Bedwick
Vice Chairman John F. Mizner, Esq.
Commissioner John J. Soroko, Esq.
Commissioner Murray Ufberg, Esq.
Commissioner Dennis A. Watson, Esq.
Pennsylvania Independent Regulatory Review Commission
555 Walnut Street, Suite 804
Harrisburg, PA 17101

Via Electronic Mail to: irrc@irrc.state.pa.us
Via Electronic Mail to: RA-DHCHAPTR27PROPREG@pa.gov

Re: Regulation #10-242: Communicable and Noncommunicable Diseases (IRRC #3490)

Dear Members of the Independent Regulatory Review Commission:

We write as Senators of the Commonwealth of Pennsylvania to express profound concerns regarding the Department of Health's proposed rulemaking regarding communicable and noncommunicable diseases under 28 Pa. Code Chapter 27.

At the outset, it is understood that the Commonwealth has a legitimate role in protecting the public from communicable disease. The Department possesses certain powers to perform that role, but those powers extend only to the authority conferred by law, not whatever additional authority it deems convenient for purposes loosely connected to public health.

Those limitations do not disappear during an actual or perceived public emergency. Measures adopted in response must remain proportionate to the demonstrated threat, reasonably tailored to the circumstances, consistently administered, and subject to meaningful transparency, oversight, and accountability. Pennsylvania's recent experience with COVID-19-era policies implemented by the Department under Governor Wolf and defended in court by then-Attorney General Shapiro demonstrated the consequences when those principles are disregarded.

The Auditor General found that the Commonwealth's business-waiver process was hastily assembled, unevenly administered, deficient in transparency and accountability, and governed by repeatedly changing guidance. Pennsylvania's closure classifications were more restrictive than corresponding federal guidance, resulting in more businesses being required to close, while

questionable decisions forced some businesses that should have been permitted to operate to remain closed.[1]

Schools fared no better. Student reading scores plummeted, and researchers studying post-pandemic academic recovery have identified Pennsylvania as among the states hardest hit. Researchers at Harvard University, Stanford University, and Dartmouth College found that, as of 2025, average Pennsylvania student achievement remained 0.56 grade levels below 2019 performance in mathematics and 0.61 grade levels below 2019 performance in reading.[2] The continuing effects upon businesses and students serve as a stark reminder of the consequences of unbridled and indiscriminate bureaucratic overreach.

During COVID-19, the Department was weaponized by the Governor as a means of controlling nearly every facet of daily life. Given no other recourse, the General Assembly proposed amending the state Constitution to limit unilateral executive authority during declared emergencies, and the voters approved it. Notwithstanding that expression of the public will, the Department now seeks through permanent regulation to legitimize an unchecked expansion of authority never clearly granted by the people's elected representatives.

If past conduct is any indication of future action, Commonwealth residents have ample reason to fear that approval of these regulations would again subordinate their fundamental rights to administrative discretion and place the exercise of that authority further beyond meaningful legislative and judicial review.

Consequently, we have reviewed with increasing alarm the expansive powers the Department seeks to claim throughout these proposed regulations. In numerous instances, we believe those claimed powers exceed the authority granted by the General Assembly and threaten fundamental constitutional and statutory protections.

Constitutional protections do not cease to operate when government acts or claims to act in pursuit of important or urgent purposes. On the contrary, constitutional and statutory restraints are most consequential when the government's objective is compelling enough to make extraordinary power seem necessary. Those powers must remain grounded in authority conferred by law, proportionate and reasonably related to demonstrated public health needs, and appropriately restrained where government action intrudes upon individual liberty, privacy, property, parental rights, religious exercise, or other protected interests.

The proposed rulemaking is lengthy and sweeping. The discussion below seeks to identify many of its more serious defects, but should not be understood as an exhaustive statement of objections to the proposal. Many of the proposed regulations are individually objectionable, but taken collectively, are intolerable.

I. DEFINITIONS

[1] Pennsylvania Department of the Auditor General, *Auditor General DeFoor: DCED Waiver Process for COVID Business Shutdown Flawed; Urges Transparency, Accountability Reforms* (Sept. 14, 2021).
[2] Center for Education Policy Research at Harvard University, Educational Opportunity Project at Stanford University & Faculty at Dartmouth College, *Pennsylvania: 2025 Education Scorecard Results* (May 13, 2026).

The Regulatory Review Act ("the Act") requires the Commission to consider the "clarity and lack of ambiguity" of a proposed regulation, as well as its need, reasonableness, statutory basis, and whether it embodies a policy decision of such a substantial nature that legislative review is warranted.[3] These requirements take on particular importance where a defined term does more than describe a regulated subject, but instead helps establish the circumstances in which an agency may exercise compulsory governmental powers.

Under these standards, several definitions in the proposed rulemaking warrant reconsideration.

1) "**Condition**." The Department proposes to define condition as "a noninfectious medical ailment or other health-related event." The Department explains that the term encompasses "events or ailments that impact public health," and cites to lead and carbon monoxide exposure, pesticide illness, and chemical releases. However, the term is not limited to those circumstances, as even the Department hints at by references to light bulbs and the use of products causing health-related events. Such open-ended language opens the door to conditions beyond those offered to justify it, potentially encompassing an extraordinary range of human circumstances. Indeed, it is difficult to imagine what is *not* included under such a term. This is consequential because "condition" is incorporated throughout the proposed regulations into provisions governing reporting, surveillance, outbreaks, investigations, entry, and other exercises of public health authority. (An "outbreak," for example, expressly includes an unusual increase in a "condition" even if that condition is not otherwise reportable.) Thus, the definition helps determine not merely what the Department may study, but when Chapter 27 authority may be exercised.

   Concern with poorly differentiated terms is not abstract. Major medical and public health organizations have characterized various matters far beyond infectious disease as within the domain of public health, including voting and elections,[4] voter registration,[5] minimum wage mandates,[6] energy policy,[7] climate change,[8] firearms and gun control,[9] violence,[10]

[3] 71 P.S. § 745.5b(a), (b)(3)-(4).
[4] Katelan Cline, David Hilden & Micah Beachy, *Ensuring Equitable Access to Participation in the Electoral Process: A Policy Brief From the American College of Physicians*, 177 Annals Internal Med. (2024), doi:10.7326/M23-2293.
[5] American Medical Association, *Support for Safe and Equitable Access to Voting*, Policy H-440.805 (modified 2022).
[6] American Public Health Association, *Improving Health by Increasing the Minimum Wage*, Policy Statement No. 20167 (Nov. 1, 2016).
[7] Ryan Crowley, Suja Mathew & David Hilden, *Environmental Health: A Position Paper From the American College of Physicians*, 175 Annals Internal Med. (2022), doi:10.7326/M22-1864.
[8] American Medical Association, *Declaring Climate Change a Public Health Crisis*, Directive D-135.966 (last modified 2024).
[9] American Medical Association, *AMA Calls for Background Checks, Wait Periods to Prevent Gun Violence* (June 15, 2016).
[10] Gary Slutkin, Charles Ransford & Daria Zvetina, *How the Health Sector Can Reduce Violence by Treating It as a Contagion*, 20 AMA J. Ethics (2018), doi:10.1001/journalofethics.2018.20.1.nlit1-1801.

incarceration,[11] immigration policy,[12] loneliness,[13] smartphone and social media use,[14] and disinformation.[15] These examples demonstrate that virtually any social, economic, behavioral, or environmental condition affecting human well-being (including those traditionally the domain of the General Assembly) has been appropriated by major health care groups as health-related.

A concept broad enough to encompass both Lyme disease and light bulbs, encephalitis and election law, collapses all semblance of legal or definitional boundaries, and therefore fails both the Act's requirements and the standards articulated in decisions such as *Commonwealth v. Stein.* In *Stein*, the Supreme Court of Pennsylvania held that "administrative rules or regulations must be written so that they fill in the details of what is otherwise a broad statutory proscription against wrongdoing. They must describe with particularity what is permitted and what is forbidden. They must create standards that eliminate vagueness and uncertainty, not create it."[16]

The Department need not look far to find precedent for defining comparable terms with greater specificity. Virginia defines the term as "any adverse health event, such as a disease, an infection, a syndrome, or as indicated by a procedure, including the results of a physical exam, laboratory test, or imaging interpretation, suggesting that an exposure of public health importance has occurred."[17] Connecticut uses the narrower term "other condition of public health significance," which it defines as a "non-communicable disease caused by a common source or prevalent exposure such as pesticide poisoning, silicosis or lead poisoning."[18] These definitions still contain elements of subjectivity, but are framed more narrowly and begin to establish a necessary connection to public health. The Department should similarly confine "condition" to a medically identifiable noninfectious disease, injury, poisoning, exposure, or other adverse health event having a defined nexus to a public health hazard, rather than the essentially unlimited category of "other health-related event."

2) "**Of public health significance**." The proposal defines this term as any disease, infection, or condition that "can reasonably be expected to lead to adverse health effects in the community." This formulation moves beyond identifiable disease to matters that merely precede or increase its risk. It therefore extends the regulation from disease control into the far less determinate realm of prevention, wellness, and ordinary behavioral risk. When coupled with the expansive definition of "condition" as any "noninfectious medical ailment or other health-related event," the term could plausibly encompass matters such as

[11] American Public Health Association, *Advancing Public Health Interventions to Address the Harms of the Carceral System*, Policy Statement No. 202117 (Oct. 25, 2021).
[12] American College of Physicians, *National Immigration Policy and Access to Health Care* (2011).
[13] Susan Jaffe, *US Surgeon General: Loneliness Is a Public Health Crisis*, 401 Lancet 1560 (2023), doi:10.1016/S0140-6736(23)00957-1.
[14] Office of the Surgeon General, U.S. Department of Health & Human Services, *Social Media and Youth Mental Health: The U.S. Surgeon General's Advisory* (2023).
[15] American Medical Association, *Addressing Public Health Disinformation Disseminated by Health Professionals*, Directive D-440.914 (modified 2022).
[16] *Com. v. Stein*, 519 Pa. 137, 546 A.2d 36 (1988).
[17] 12VAC5-90-10.
[18] Conn. Agencies Regs. § 19a-36-A1(35).

consumption of sugary beverages, salt intake, diet, physical inactivity, screen use, or innumerable other everyday behaviors associated with some increased risk of adverse health effects. Although some flexibility is appropriate to address unforeseen threats, no threshold of severity, prevalence, magnitude, or materiality is provided. Such boundless terminology must be given narrower limits, and objective thresholds should be established commensurate with the governmental authority this designation may trigger.

3) "**Outbreak**." The proposed definition extends an "outbreak" to an unusual increase in any disease, infection, or "condition," including one that is not otherwise reportable, whenever cases exceed what a person required to report "would expect to see." Epidemiological practice may not always permit a fixed numerical threshold. But where an "outbreak" may serve as a predicate for investigation and other governmental authority, the combination of an otherwise nonreportable "condition" and a reporter's subjective expectation provides insufficient regulatory certainty. The definition should be tied to an objectively identifiable epidemiological circumstance suggesting transmission, common exposure, common etiology, or another defined public health hazard.

4) "**Physician**" and "**health care practitioner**." The Department proposes throughout the regulations to replace references to a "physician" with the substantially broader term "health care practitioner," defined as any individual authorized by a Commonwealth license, permit, certificate, or registration to practice "some component of the healing arts." The Department explains that this change recognizes that professionals other than physicians, including certified registered nurse practitioners, may diagnose and treat patients within their lawful scopes of practice. However, there is a difference between recognizing lawful functions of nonphysician practitioners and erasing physicians as a profession altogether, or subsuming them into subordinate categories.

   The General Assembly enacted the DPCL against a professional landscape that already included nurses, midwives, institutional administrators, and other nonphysician health professionals, and the statute refers to those persons expressly where it intends to do so. Section 4, for example, separately addresses reporting obligations involving physicians, heads of hospitals, laboratory directors, nurses, midwives, and others.[19] Section 13 references other persons permitted to attend pregnant women or report births and deaths.[20] The General Assembly's use of "physician" therefore cannot automatically be presumed to have meant any person who happens to possess a health-related professional credential. A categorical regulatory substitution of "health care practitioner" for "physician" risks an impermissible expansion of statutory definition through regulation rather than legislation. The practice of medicine remains physician-led. This distinction can be preserved in regulations by referring where appropriate to "physicians and other health care practitioners."

5) "**Surveillance**." The Department proposes to replace the existing definition of "surveillance," which is limited to scrutiny of the occurrence and spread of disease pertinent to its effective control, with the systematic collection and analysis of "health-related data" considered essential to public health practice. The new definition is materially broader in both subject

[19] 35 P.S. § 521.4.
[20] 35 P.S. § 521.13.

and purpose. As with "condition," the phrase "health-related" provides little meaningful limitation. A nexus should be retained between surveillance and data that is reasonably necessary to carry out a defined statutory public health function.

II. MASS COLLECTION OF EMERGENCY DEPARTMENT HEALTH INFORMATION

The Department proposes revising § 27.4a to require every hospital to transmit emergency department visit data to the Department's syndromic surveillance system "as near to real-time as possible," and no later than 24 hours after presentation. The required information includes age or date of birth, gender, race, ethnicity, chief complaint, a patient or visit identifier, home ZIP code, diagnosis codes and descriptions, disposition, death status, and "other data elements deemed necessary by the Department." This requirement is not limited to patients diagnosed with, exposed to, or suspected of having a reportable disease.

Both the U.S. and Pennsylvania Constitutions provide for the rights of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures.[21] Those rights and liberties are not to be burdened or abridged in the absence of due process.[22] The Supreme Court of Pennsylvania has held that these protections encompass a reasonable expectation of privacy in medical records and a constitutional interest in avoiding compelled disclosure of personal medical information. Governmental intrusion upon these interests is subject to constitutional scrutiny, requiring the individual's privacy interest to be weighed against the governmental interest asserted to justify the intrusion.[23]

The Third Circuit Court of Appeals has further recognized a constitutional privacy interest under the Fourteenth Amendment in avoiding governmental disclosure of personal medical information. Medical records containing intimate personal information fall within the protected zone of privacy, and governmental demands for such information require the individual's privacy interest to be balanced against the government's asserted need for disclosure.[24] That analysis considers, among other things, the sensitivity of the information, the potential harm from nonconsensual disclosure, the relationship in which the information was generated, safeguards against further disclosure, the government's need for access, and whether an express statutory mandate supports disclosure.

Proposed § 27.4a raises grave concerns under these principles. It would require hospitals to transmit near real-time information concerning every emergency department encounter in Pennsylvania, without regard to whether the patient has, or is suspected of having, a reportable disease or condition. This information is generated during confidential treatment relationships, often under circumstances in which highly sensitive information must be disclosed to obtain appropriate care. The proposed regulation would make governmental acquisition of such

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[21] U.S. Const. amend. IV; Pa. Const. art. I, § 8.
[22] U.S. Const. amend. XIV, § 1; Pa. Const. art. I, § 1.
[23] *Stenger v. Lehigh Valley Hosp. Ctr.*, 530 Pa. 426, 609 A.2d 796 (1992); *In re June 1979 Allegheny Cnty. Investigating Grand Jury*, 490 Pa. 143, 151, 415 A.2d 73 (1980); *Com. v. Riedel*, 539 Pa. 172, 651 A.2d 135 (1994); *Com. v. Shaw*, 564 Pa. 617, 770 A.2d 295 (2001).
[24] *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570 (3d Cir. 1980).

information mandatory, without patient consent, individualized suspicion, a warrant, or any nexus to a particular disease or public health investigation.

This conversion takes on a different connotation when one considers the consequences for noncompliance. The DPCL provides that a violation of it or its regulations constitutes a summary offense punishable by a fine of $25 to $300, together with costs, and permits imprisonment for up to 30 days upon default of payment. The statute further permits prosecution to be instituted by the Department, a local health authority, or any person having knowledge of the violation.[25] Not only does the Department presume to convert voluntary submission into mandatory performance, but it does so under color of legal penalties. These consequences apply throughout the proposal wherever Chapter 27 creates an affirmative duty or prohibits obstruction or interference. A conviction would also create a criminal record that, depending upon the profession and circumstances, may carry collateral professional or licensing consequences.

The Department identifies no corresponding deficiency in the existing system that this new mandate would remedy. To the contrary, the Department states that all Pennsylvania hospitals already transmit this data voluntarily and therefore concludes that the proposed requirement will have "no impact on hospitals." If so, the principal legal effect of the amendment is not to obtain information presently unavailable to the Department, but to convert its submission from voluntary to compulsory. The fact that a hospital presently elects to participate in a surveillance system does not establish that the Commonwealth may compel the hospital to disclose its patients' medical information, nor does a patient's disclosure of information for purposes of diagnosis and treatment constitute consent to its acquisition by government.

Given the breadth of the information collected, the absence of a disease-specific predicate, and the open-ended authority to demand additional data, the public interest in imposing this new compulsory regime has not been adequately demonstrated. Accordingly, § 27.4a should be revised or withdrawn absent a substantially greater showing of necessity, statutory authority, and safeguards commensurate with the information compelled. At minimum, any revised provision should limit mandatory reporting to information reasonably necessary for a defined public health purpose, establish why identifiable rather than deidentified information is necessary, provide definite rules governing access, retention, linkage, secondary use, redisclosure, and destruction, and remove open-ended authorizations for "other data elements deemed necessary by the Department."

III. EXPANDED DISEASE REPORTING AND ACCELERATED TIMEFRAMES

The proposed rulemaking substantially expands the diseases, infections, and conditions subject to mandatory reporting. The Department states that proposed § 27.21a will require health care practitioners and facilities to report an additional 73 diseases, infections, and conditions, while § 27.22 will impose 53 additional reporting requirements upon clinical laboratories.

While many of these additions reflect developments in epidemiology and national disease surveillance since Chapter 27 was last comprehensively revised, they nevertheless impose significant new reporting obligations and corresponding compliance costs upon the regulated

[25] 35 P.S. § 521.20(a)-(b).

community. The Department itself estimates the cumulative increase in reportable conditions as rising from 52 to 125—a 140 percent increase.

The proposal also accelerates numerous existing reporting deadlines. Some changes, particularly immediate reporting for diseases such as anthrax, measles, plague, and smallpox, are understandable. Others move existing five workday requirements to 24 hours, including syphilis, tetanus, or *Candida auris*. While expedited reporting is plainly warranted for certain rapidly transmissible or high-consequence diseases, the Department should explain the public health necessity for each material acceleration, and whether and why less intrusive timelines were not considered.

In addition to more than doubling the number of reportable conditions and accelerating numerous reporting deadlines, the proposal provides practitioners, facilities, and laboratories with no apparent post-promulgation implementation period to make the changes to automated reporting systems or workflows before additional reporting requirements become legally effective. (This contrasts with the delayed effective date the Department has provided itself to implement its proposed new birth defects registry under § 27.37 "to accommodate the development and full implementation" as well as an additional 30-day period after publication of notice that the registry is operational.) Regulated practitioners, facilities, and laboratories should be afforded a reasonable implementation period as well.

These substantially expanded duties and shortened deadlines are backed by the enforcement consequences discussed above, further underscoring the need for precise requirements, adequate notice, and a reasonable implementation period.

Regarding cost, the Department acknowledges an increased burden of compliance, including either modifications to automated reporting systems or additional staff time for manual reporting. While this letter will address the adequacy of the overall fiscal analysis later, it bears noting here that the Department states these changes will financially affect practitioners and facilities, but that it lacks the data to quantify the cost. Peculiarly, the Department then affirmatively assigns a cost of zero to the numbers it expressly does not have. The Act requires estimates of the direct and indirect costs imposed upon the private sector, including consideration of the nature and estimated cost of additional reporting, recordkeeping, and other paperwork required for compliance.[26] The asserted absence of sufficient data to quantify these costs does not relieve the Department of its statutory obligations to assess them. The Department must identify what steps were taken to assess these costs, including any comments from the regulated community. Due consideration must be given to the impact on physicians and other health care practitioners by more than doubling their reporting requirements.

These additional burdens come at a time when Pennsylvania's health care system is already under considerable strain. Thirty-seven percent of Pennsylvania hospitals are operating at a loss, and twenty-five hospitals have closed since 2016.[27] The Pennsylvania Health Access Network separately identified seventy-eight hospital closures or reductions in core services during the past

[26] 71 P.S. §§ 745.5(a)(4)-(5), 745.5b(b)(1).
[27] Oliver Wyman, *Time to Act: What the Future Holds for Pennsylvania's Hospitals, Patients, and Communities* (Jan. 2026).

twenty-five years, including twenty-six in rural counties.[28] Workforce shortages are also directly affecting patient care, with hospitals reporting significant and persistent shortages of nurses, respiratory therapists, and medical assistants. Up to one-third of direct care worker positions remain unfilled, as do approximately one in five registered nurse positions, with higher shortages in rural areas.

Seventy percent of hospitals reported longer emergency department wait times because of these shortages, while 68% reported delayed appointments or procedures. Among nursing homes, 53% report having to limit admissions or cap their census due to the Department's recent state staffing ratio mandates, and 42% report having to limit or deny admissions. Those restrictions contribute to hospital-discharge backlogs and further reduce available capacity throughout the health care system.[29]

The Department is neither unaware nor a passive observer of these conditions, particularly where its own staffing mandates contribute to backlogs and shortages. Nor has the administration been reluctant to highlight these struggles in furtherance of its objections to federal policy. Its Department of Human Services has developed and published detailed projections of the effects of federal policy changes, including estimates of SNAP and Medicaid coverage losses for every congressional, Pennsylvania House, and Pennsylvania Senate district, together with county-level enrollment, spending, and economic impact data.[30] Yet, when required by the Act to assign a price tag to its own arduous mandates, the Department falls woefully short. The Commonwealth plainly possesses both the data and analytical capacity to evaluate policy impacts with considerable specificity. Equal rigor must be applied to burdens imposed from Harrisburg inside the state, particularly where the Department risks exacerbating the very shortages, delays, staff burnout, and loss of access the administration invokes in other contexts.

Notably, the sole reporting duty of which providers are relieved is the duty to report Lyme disease, which the Department asserts is now functionally measured only by lab-confirmed cases. This exclusion is made more conspicuous since the proposal (laudably) requires provider reporting of other tickborne diseases, including comparatively rare infections caused by *Borrelia miyamotoi*, Bourbon virus, and Heartland virus.

Lyme disease remains the most commonly reported tickborne disease in Pennsylvania,[31] and the most common vector-borne disease in the United States according to the CDC.[32] The Department continues to issue health advisories warning of increased emergency department visits for Lyme

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[28] Pennsylvania Health Access Network, *47 Pennsylvania Hospitals Rely on Medicaid to Stay Open* (May 21, 2025).
[29] Hospital and Healthsystem Association of Pennsylvania, LeadingAge PA & Pennsylvania Health Care Association, *Care Across the Continuum: How Health Care Workforce Shortages Affect Pennsylvanians' Access to Care* (Apr. 2025).
[30] Pennsylvania Department of Human Services, *Data Dashboards and Reports*, Projected Medicaid & SNAP Losses Due to Federal Changes (last visited Sept. 18, 2026).
[31] Pennsylvania Department of Health, *Dashboard and Tickborne Disease Data*, Tickborne Diseases Dashboard (last visited Sept. 10, 2026).
[32] CDC, *Surveillance for Lyme Disease After Implementation of a Revised Case Definition — United States, 2022*, 73 MMWR 118, 118–23 (Feb. 15, 2024).

and other tickborne diseases, and advising physicians and other providers to "have a heightened clinical suspicion for tickborne diseases in persons with clinically compatible symptoms."[33]

Laboratory reporting alone provides an incomplete epidemiological picture of Lyme disease. A 2024 study published in the CDC's *Emerging Infectious Diseases* found that laboratory surveillance may miss clinically diagnosed early Lyme disease, produce nonspecific results, and fail to distinguish an active disease from past infection. The researchers found that supplementing laboratory results with physician-generated information such as electronic health record data, clinical diagnoses and antibiotic prescriptions, substantially improved surveillance and could provide a more complete picture of Lyme disease incidence.[34]

Rather than codifying laboratory-only surveillance, the Department should restore clinically informed components of Lyme disease surveillance, whether through physician or other practitioner reporting, or automated EHR-based reporting that captures diagnoses and treatment while minimizing provider burden.

More broadly, while the Department asserts that it has "chosen, throughout the proposed regulations, to align with federal guidance from the CDC," that alignment is not consistent. The Department has, for example, elected in several instances to follow American Academy of Pediatrics recommendations rather than those of the Advisory Committee on Immunization Practices, relying principally on a Commonwealth Executive Order. (In rescinding its reliance upon ACIP's Child and Adolescent Immunization Schedule, the Department cites *Protz v. Workers' Compensation Appeal Board* and the concern against delegating its rulemaking authority to the future recommendations of outside entities. In contrast, the Department appears to rely on outside federal definitions elsewhere, such as determinations by DHHS and USDA regarding threats posed by biological material in its definition of "selected agent or toxin.")

In disease reporting, the Department expressly acknowledges that hepatitis D and hepatitis E are not nationally notifiable conditions but nevertheless proposes mandatory reporting of acute and chronic cases. (Conversely, it declined to add pinworm reporting in part because the condition is not nationally notifiable and does not appear to be commonly reportable in other states.) These changes are not reflected in the Department's response to the Regulatory Analysis Form's requirement to identify provisions more stringent than federal standards and the compelling Pennsylvania interest supporting them. Instead, the Department states generally that its disease reporting requirements align with the CDC's NNDSS. The Department should identify all material departures from the federal or national standards upon which it relies, explain the Pennsylvania-specific basis for each, and apply the criteria consistently.

Separately, the Department should clarify whether transferring certain metabolic and genetic conditions from § 27.21a to § 27.30 inadvertently narrows existing reporting requirements. Current regulations require, for example, reporting of Maple Syrup Urine Disease in children

[33] Pennsylvania Department of Health, *Lyme Disease and Other Tickborne Diseases in Pennsylvania*, Health Advisory No. 821, 2026-PAHAN-821-04-22-ADV (Apr. 22, 2026).
[34] Kshema Nagavedu et al., *Electronic Health Record Data for Lyme Disease Surveillance, Massachusetts, USA, 2017–2018*, 30 Emerging Infectious Diseases (2024), doi:10.3201/eid3007.230942.

under five years of age, while proposed § 27.30 instead incorporates reporting under the Newborn Child Testing Act, which defines a "newborn child" as a child less than 28 days old.

The Department should further clarify whether laboratory reporting requirements distinguish an initial reportable finding from repeat or expected results generated in the course of monitoring an already-known case. (See, for example, the language in § 27.77, where information "need not repeat information contained in a previously submitted verification.") Without such a distinction, laboratories may be required to repeatedly report results that provide no additional epidemiological information. Similar consideration should be given to conditions such as carbon monoxide poisoning, where the Department's stated purpose is to identify and prevent further exposure, but the proposed threshold appears to capture results arising from known intentional exposures, fires, or other circumstances in which the source is already established and no further public health intervention is indicated.

Within this section, the Department also proposes expanding data collection to include race and ethnicity for all laboratory reports—a mandate it concedes will require more work from laboratories. This expansion is principally justified by the Department not by what is epidemiologically relevant, but by reference to identifying "health equity issues," "vulnerable populations," and resource allocation. This warrants heightened scrutiny; federal civil rights law prohibits covered health programs from denying or providing different services or benefits on the basis of race, color, or national origin, and guidance from Health & Human Services expressly provides that race and ethnicity should not be used as criteria in allocating scarce medical resources.[35] If such categorical data is to be collected, the Department must identify which epidemiological or other nonprohibited purposes justify it, and clarify that data will not be used to determine individual eligibility, priority, or access to health services or resources on the basis of race or ethnicity.

Taken together, these substantial expansions of reporting obligations, unexplained departures from national standards, unresolved questions of scope and implementation, and unquantified costs prevent a finding that the proposed regulation, in its present form, is in the public interest. The Department should substantially revise the proposal to address the concerns identified above. If it does not, the Commission should disapprove the regulation.

IV. MANDATORY VACCINE REPORTING AND REGISTRATION

Under § 27.36, the Department proposes expanding participation in the Commonwealth's immunization registry by transferring it from its current, voluntary system into mandatory reporting of individually identifiable immunization information by health care providers. As with emergency department data, this represents a material expansion of governmental collection of medical information and warrants corresponding scrutiny. As recounted earlier, Pennsylvania

[35] U.S. Dep't of Health & Human Servs., Office for Civil Rights, *Discrimination on the Basis of Race, Color, or National Origin (including LEP)*; U.S. Dep't of Health & Human Servs., *Interim Guidance on Critical Care Resources Allocation for Direct-Service IHS Hospitals* 4 (Jan. 6, 2021); U.S. Dep't of Health & Human Servs., Office for Civil Rights, *Guidance on Federal Legal Standards Prohibiting Race, Color and National Origin Discrimination in COVID-19 Vaccination Programs* (Dec. 2021).

recognizes a substantial privacy interest in medical information. The fact that the information has been disclosed to a health care provider for treatment does not extinguish that interest.

Mandatory reporting also changes the nature of the privacy interest at stake. A patient's immunization history ordinarily exists in medical records maintained by providers with whom the patient has established a treatment relationship. The proposed rule would require that information to be transmitted to and consolidated within a government-maintained database. As recounted earlier, the courts have long recognized that governmental accumulation of personally identifiable medical information implicates privacy interests and requires meaningful safeguards against unwarranted disclosure. Those concerns are heightened where participation is made compulsory rather than voluntary.

History has shown that immunization registries are not necessarily passive repositories. Philadelphia has previously used its immunization registry to identify children for individualized reminder letters and community-based outreach,[36] and its current program uses its "PhilaVax" information to identify infants lacking recorded immunizations for direct outreach to their parents.[37] Centralized immunization data therefore is not merely stored for clinical recordkeeping; it can be and has been used to identify particular individuals for public health intervention. The Department underscores this concern when it states the immunization information system will assist in "supporting recommended immunizations." That use is materially different from traditional communicable disease investigation. Using a consolidated government medical database to identify and contact an individual who may neither have contracted nor been exposed to a disease, solely because the individual's record does not reflect an immunization recommended by whichever advisory body the Department currently follows, presents a different privacy question.

The experience of the COVID-19 pandemic further demonstrates that vaccination information can acquire governmental uses extending substantially beyond mere clinical recordkeeping. During COVID-19, state and local governments conditioned access to employment,[38] education,[39] restaurants, entertainment venues, and other activities upon proof of vaccination.[40] Philadelphia's PhilaVax records were a designated form of proof to satisfy those limits. The establishment of a statewide registry alone may not establish the intent that PIERS become a passport system, but it does provide the architecture for it. History underscores the importance of defining prospectively the permissible uses and disclosures of information collected through a mandatory statewide registry. The legislative history of such endeavors in other states also

[36] Sarah Wilcox et al., *Registry-Driven, Community-Based Immunization Outreach: A Randomized Controlled Trial*, 91 Am. J. Pub. Health 1507 (2001), doi:10.2105/AJPH.91.9.1507.
[37] Philadelphia Department of Public Health, Philadelphia Immunization Program, *Programs: PhilaVax & Community Based Outreach* (last visited Sept. 10, 2026).
[38] City of Philadelphia, *City Announces Vaccine Mandate for All City Employees and Contractors* (Nov. 19, 2021).
[39] City of Philadelphia, *COVID Vaccines Mandated for Healthcare Workers and those at Philly Colleges and University* (Aug. 13, 2021).
[40] Philadelphia Department of Public Health, *City of Philadelphia Announces Food Establishment Vaccine Mandate* (Dec. 13, 2021).

suggests that such actions are often of such a substantial policymaking impact as to require legislative, rather than regulatory action.[41]

Recent events further demonstrate the sensitivity of vaccination status and the importance of clear rules governing when individually derived immunization information may be publicly disclosed. The regulation should make clear under what circumstances, if any, the Department may disclose identifiable or reasonably identifiable vaccination status publicly, and what legal and procedural safeguards govern such a disclosure.

The proposal also raises a substantial question of necessity and potential redundancy. Immunization information is already maintained in patient medical records, and the proposed regulations elsewhere intend to grant the Department broad authority to obtain and review those records when investigating communicable disease. Proposed § 27.36 goes materially further: rather than permitting access when a public health need arises, it requires the routine transmission and centralized tracking of each individual's immunization history in advance of any investigation, exposure, outbreak, or other particularized public health need. If the Department can already obtain the underlying records when necessary, it should explain why universal prospective collection of the same information in an individually identifiable government database is additionally necessary.

A centralized registry may offer administrative convenience and permit consolidation of records across providers, but convenience is not itself sufficient to resolve the privacy question. There is a meaningful difference between governmental access to medical information when a defined public health need arises and continuous governmental tracking of the same information merely because it may prove useful in the future. That distinction is particularly important where the registry is intended not simply to reproduce a medical record, but to aggregate information across providers, identify individuals according to immunization status, and potentially facilitate subsequent governmental outreach or other interventions.

Any residual provisions surviving Department revision should likewise address access and secondary use. The Department should specify whether identifiable PIERS information may be disclosed to or queried by other Commonwealth agencies, schools, employers, licensing bodies, law enforcement, contractors, or other third parties; whether it may be matched against other governmental databases; whether it may be used to determine compliance with present or future vaccination requirements; and whether the system may generate credentials or verification of vaccination status for nonclinical purposes. The CDC's own guidance concerning immunization registries emphasizes purpose limitations, authorized user restrictions, limitations on disclosure, penalties for misuse, and meaningful opt-out or access limitation provisions.[42]

[41] See, e.g., the enabling statutes in New York (N.Y. Public Health Law § 2168), New Jersey (N.J.S.A. 26:4-131), Maryland (Md. Code, Health–General § 18-109), Virginia (Va. Code Ann. § 32.1-46.01) and Michigan (Mich. Comp. Laws § 333.9207).

[42] Centers for Disease Control and Prevention, *Immunization Information Systems Resources*, Privacy and Confidentiality (Mar. 30, 2026); Centers for Disease Control and Prevention, *IIS Frequently Asked Questions* (Apr. 7, 2026).

The proposed changes to § 27.36 heighten the importance of informed consent and choice, and clear, meaningful notice of whether or not to participate. If provider reporting is to be made mandatory unless an individual affirmatively declines participation, the regulation should require clear and conspicuous notice of the individual's right to opt out, and the consequences if they do not. This bears directly upon the asserted public health benefit of the rule. Consent and opt-out provisions are particularly important to certain religious communities, victims of domestic violence, and others. The regulation should require conspicuous notice of that right before recording and transmission of identifiable information and should explain what happens to information already contained in the system following an opt-out. Indeed, while the need for opting out is essential, the entire regulatory framework would better serve these individual concerns by being opt-in. Mandatory inclusion without meaningful notice and choice could undermine public confidence or discourage vaccination among populations already hesitant to receive recommended immunizations—the very purposes asserted by the Department.

All of the foregoing applies primarily to patients and their medical privacy. The implications for providers must also be considered. As mentioned earlier, affirmative duties carry with them fines and potential prison time. In practical terms, for the practitioners, facilities, and other vaccinators that do not voluntarily participate in PIERS today (approximately 4,750 by the Department's estimate), the proposal transforms a presently lawful abstention into an affirmative duty, subject to criminal prosecution. It is far from obvious that this is either a practical outcome, or one authorized under the DPCL.

The administrative burden of compliance is likewise substantial. The Department expressly acknowledges that compliance may require additional staff or information technology support, and that the resulting costs will vary according to vaccination volume and staffing. It then states that it lacks sufficient data to quantify those costs, and estimates "no overall financial impact." Once again, absence of evidence is not evidence of absence. The Act requires estimates of direct and indirect costs to the private sector and consideration of additional reporting, recordkeeping, paperwork, legal, accounting, and consulting requirements. The absence of sufficient data does not relieve the Department of that statutory obligation.

The Department should also assess whether some presently nonparticipating providers may respond to these new costs by reducing or discontinuing immunization services altogether rather than establishing the systems necessary to comply. Vaccination may represent only a small portion of the services furnished by some affected practices, and the Department should not assume, without supporting data, that imposing a new reporting mandate backed by criminal penalties will leave provider participation and patient access unchanged.

For these reasons, the proposed mandatory reporting and centralized collection of identifiable immunization information does not presently satisfy the public interest criteria of the Regulatory Review Act. The Department has not adequately demonstrated the necessity for universal prospective collection, defined the permissible uses and disclosures of the information with sufficient clarity, established adequate safeguards against secondary use or misuse, assessed less intrusive alternatives, or adequately quantified the costs imposed upon affected providers. These deficiencies bear directly upon the regulation's reasonableness, necessity, clarity and lack of ambiguity, economic and fiscal impact, and protection of the public health, safety and welfare.

Accordingly, it should be withdrawn or revised to conform to these requirements or be disapproved if it is not.

V. BIRTH DEFECTS REPORTING AND REGISTRATION

Proposed § 27.37 would create a statewide birth defects registry and require every health care practitioner and health care facility to report diagnosed birth defects, congenital abnormalities, and abnormal neonatal screening findings. Whether or not comprehensive birth defect surveillance is desirable as a matter of policy, the proposal raises substantial questions concerning statutory authority, duplication of existing programs and reporting, the absence of commensurate safeguards, the broadness of the reporting criteria, and its unquantified public and private costs.

Concerning statutory authority, the Department relies upon section 16(a) of the DPCL, which authorizes regulations concerning the identification, reporting, prevention, and control of communicable and noncommunicable diseases. However, the proposed reporting appears to extend beyond such diseases, including structural variations, congenital deformations, chromosomal findings, fetal deaths, and abnormal neonatal screening findings. Furthermore, while the Department cites the fact that Pennsylvania is the only state in its region that does not have a birth defects registry, it does not mention that comparable birth defects reporting or surveillance systems were generally enacted via statute rather than inferred from generalized regulatory authority. (These states include Delaware,[43] Maryland,[44] Michigan,[45] New Jersey,[46] North Carolina,[47] Ohio,[48] Rhode Island,[49] Virginia,[50] West Virginia,[51] and Massachusetts.[52] Even New York, whose registry apparently originated in regulation, now rests upon express statutory authorization for the reporting of birth defects.[53]) In identifying the perceived lack of a registry relative to other states, the Department also supports the conclusion that this is an area of substantive public policy requiring legislative authorization, not mere regulatory inference.

Moreover, the proposed universe of conditions made reportable is extraordinarily broad. The Department states that its categories correspond generally to ICD-10-CM codes Q00–Q99. The proposal appears to exceed the Q00–Q99 category by including "abnormal findings on neonatal screening," which falls within the ICD-10 P09 category. Either way, the proposal encompasses hundreds of classifications, including common or minor findings such as tongue ties (ICD-10-CM Q38.1), prominent ears (ICD-10-CM Q17.5), accessory nipples (ICD-10-CM Q83.3), congenital birthmarks (ICD-10-CM Q82.5), flat feet (ICD-10-CM Q66.5), webbed toes (ICD-10-

[43] 16 Del.C. § 203.
[44] Md. Code Ann., Health – Gen. § 18-206.
[45] Mich. Comp. Laws § 333.5721.
[46] N.J.S.A. 26:8-40.21.
[47] N.C.G.S.A. § 130A-131.16.
[48] Ohio Rev. Code § 3705.30.
[49] R.I. Gen. Laws § 23-13.3-1, *et seq.*
[50] Va. Code Ann. § 32.1-69.1.
[51] W. Va. Code § 16-40-2.
[52] Mass. Gen. Laws ch. 111, § 67E.
[53] N.Y. Pub. Health Law § 2733.

CM Q70.3), and undescended testes (ICD-10-CM Q53).[54] It is not obvious whether the Department, on its own initiative, must be in the business of tracking every accessory nipple, flat foot, webbed toe, or undescended testicle in the Commonwealth, particularly at the expense of both taxpayers and the practitioners and facilities required to report them.

The proposal also does not clearly establish an age or temporal limit for reportable diagnoses. A congenital condition may be present at birth but remain undetected or undiagnosed until childhood or even adulthood. The Department should clarify whether proposed § 27.37 applies only to conditions diagnosed at or shortly after birth, or whether practitioners and facilities must report congenital abnormalities whenever they are first diagnosed, potentially years or decades later. Without such a limitation, the proposal could impose a continuing reporting obligation extending far beyond newborn care and substantially increase both the number of covered practitioners and the costs of compliance.

The extraordinary breadth of the reporting universe is especially consequential because once again, the obligation is mandatory and carries the enforcement consequences described above.

The Department also has not demonstrated why a new reporting system is necessary or how it will interact with information already collected through birth and fetal death certificates, hospital records, newborn screening, Medicaid claims and encounter data, and the Enterprise Data Dissemination Informatics Exchange (EDDIE). Pennsylvania already operates a Newborn Screening and Follow-Up Program as established by the General Assembly, and the Department maintains and updates through regulation the conditions included in the screening panel. Pennsylvania requires dried blood spot screening for numerous metabolic, endocrine, hematologic, genetic, and other disorders, together with screening for critical congenital heart defects and hearing loss. The Department already receives abnormal results and conducts follow-up activities. These requirements substantially overlap with the proposed reporting of congenital abnormalities and abnormal neonatal-screening findings. (By comparison, West Virginia's enabling statute expressly prohibits its birth defects system from requiring providers and facilities to report information already required under another provision of state law.) Before imposing another reporting mandate, the Department should provide a condition-by-condition comparison between proposed § 27.37 and its existing screening, vital records, claims, and administrative data sources.

Of note, existing newborn screening requirements also contain procedural protections not apparent in proposed § 27.37. Chapter 28 regulations include specifics regarding confidentiality, and express religious exemptions from newborn screening and procedures for documenting a parent's objection. The Department has not explained why information obtained through the proposed registry should be collected without comparable protections, provisions for meaningful notice and consent for such reporting, or why and how the creation of a second reporting pathway might interact with or bypass existing safeguards applicable to current programs.

Finally, the Department's economic analysis is insufficient. It acknowledges that practitioners and facilities may need to develop electronic reporting systems or assign personnel to make

[54] Centers for Disease Control and Prevention, National Center for Health Statistics, *ICD-10-CM Tabular List of Diseases and Injuries* (Apr. 1, 2022).

manual reports, but states that it lacks sufficient data to estimate either expense. The inability to quantify a known mandate does not establish that the mandate has no fiscal impact. In evaluating impacts on small businesses, the Department merely asserts that small businesses will be affected in the same manner as larger ones. That oversimplification entirely misses the point of the Act's requirement to assess small business impacts independently, and to consider utilizing regulatory methods that will accomplish its objectives while minimizing adverse impact on small businesses. Even nominal reporting requirements, much less the potentially voluminous mandate proposed here, can impose substantially greater proportional burdens on independent practices and rural facilities whose administrative staff and technological resources are far more limited than those of large health systems. Merely asserting that every entity is subject to the same mandates is not the same as assessing the unique operational burdens assumed by small businesses. That disproportionate effect analysis is the very reason a regulatory analysis separately asks about small business impacts.

Disproportionate impact is a concept well understood and frequently applied by the Department in other policy contexts. If it proceeds, the Department should quantify the expected number of reports, identify all affected entities, estimate implementation and recurring compliance costs, evaluate less burdensome alternatives, and conduct a meaningful analysis of the disproportionate effect on small providers and facilities.

The Department was considerably more specific when calculating its own expenses. It estimates a one-time cost of $150,000 to add a registry module to its existing newborn-screening system; annual maintenance costs of approximately $30,000; annual data-hosting costs of between $40,000 and $100,000; approximately $20,000 to $30,000 for training during at least the first two years; and $1,523,977 for staffing and initial operating costs during the first year. Thus, the Department identifies more than $1.7 million in first-year governmental costs while leaving entirely unquantified the corresponding costs imposed upon every affected practitioner and facility.

The Department provides no meaningful projection of its own costs beyond the first year. If staffing expenses remain near the amount estimated for the first year, the registry could cost taxpayers approximately $8.2 million to $8.5 million over five years and $16.1 million to $16.8 million over ten years, even without accounting for inflation, salary increases, system expansion, replacement costs, or increased data-storage needs. Although the Department anticipates seeking between $300,000 and $600,000 in CDC funding, it acknowledges that the grant is not guaranteed and does not establish whether such funding would be one-time, recurring, or available throughout the registry's operation.

These unanswered questions of statutory authority, legislative prerogative, scope, duplication, safeguards, and public and private cost leave the Department far short of demonstrating that proposed § 27.37 is in the public interest. The creation of a compulsory statewide medical registry of this breadth and expense is a substantive legislative judgment, particularly where comparable states generally acted through express statutory authorization. Proposed § 27.37 requires substantial revision if it is to proceed at all; absent a clear legislative mandate and satisfactory resolution of these deficiencies, it should be withdrawn or disapproved.

VI. DISEASE CONTROL MEASURES

Few provisions of the proposed rulemaking warrant greater scrutiny than the expansion of the Department's disease control authority. Each will be taken in its turn below.

§ 27.60. Disease control measures.

Existing provisions under § 27.60 authorize specified measures including isolation, surveillance, segregation, quarantine, and modified quarantine, as well as residual authority to employ other measures considered appropriate "for the surveillance of disease" when "necessary to protect the public from the spread of infectious agents." The proposed regulation expands this authority to include "conditions," and any other disease control measure the Department considers appropriate to prevent, contain, or mitigate the spread of diseases or toxins.

The significance of the word "any" should not be understated. Although the existing phrase is broad, the Supreme Court held in *Corman v. Acting Secretary of the Pennsylvania Department of Health* that the doctrine of *ejusdem generis* provides at least some constraint upon its meaning by limiting otherwise broad catch-all verbiage to a class of preceding, specifically enumerated measures.[55] The Court further recognized that the existing regulation constrained residual disease control measures by requiring them to be "appropriate for the surveillance of disease."

It is precisely these legal constraints which the Department now endeavors to escape by broadly expanding the universe of pretexts under which catch-all authority may be exercised. Rather than limiting residual measures to surveillance and protection against the spread of infectious agents, the Department proposes to authorize any measure it considers appropriate for the substantially broader purposes of prevention, containment, or mitigation. The significance of the expansion is confirmed by the Department itself, which acknowledges the *Corman* decision influenced the amendment, and specifically the schoolwide masking mandate at issue in that case. At the time, the Department attempted to exercise broad authority under the existing language and was rebuffed; now, it proposes expressly broader language to reinstate its authority to impose measures of that kind.

That proposal is particularly discordant with the position Governor Shapiro publicly took before assuming office. As Attorney General, his office defended the Wolf Administration's school mask mandate in court, arguing that it was necessary to protect schoolchildren and their families and prevent schools from becoming COVID-19 "super-spreader sites." Yet while campaigning for Governor in 2022, Shapiro expressly rejected mask and vaccine mandates and said officials had "got it wrong" with school and business shutdowns. He instead advocated an approach that would "educate, empower, and respect people's personal decisions and respect their personal freedom to make those choices."[56] This raises the question of why an administration led by a Governor who repudiated those compulsory exercises of power is now seeking regulatory authority to reimpose them.

The inclusion of "condition" further compounds this concern. As discussed above, that term encompasses any "noninfectious medical ailment or other health-related event." When combined

[55] *Corman v. Acting Sec'y of Pennsylvania Dep't of Health*, 671 Pa. 345, 266 A.3d 452 (2021).
[56] Marc Levy, *Josh Shapiro Breaks with Democrats on COVID-19 Policies*, Phila. Inquirer (Aug. 30, 2022).

with apparently undefined terms such as "prevention" and "mitigation," the resulting authority appears to have few if any textual limits, and is capable of encompassing virtually any precaution that might, in the Department's reckoning, reduce the incidence, transmission, or consequences of disease or another health-related event, including measures imposed universally upon persons neither known nor suspected of being infected or exposed.

This is particularly consequential because disease control measures can implicate freedom of movement, bodily autonomy, medical decision making, religious exercise, education, employment, property, assembly, and access to public accommodations. Yet the proposed language does not identify the universe of permissible measures, distinguish measures directed at infected or exposed persons from measures imposed upon the public generally, prescribe a threshold of disease severity necessary to invoke them, or expressly require consideration of less intrusive alternatives. Instead, the operative limitation is principally what the Department itself "considers appropriate." That is discretion of extraordinary latitude over interests protected by both the United States and Pennsylvania Constitutions, and it is not discretion which has been limitlessly delegated to the Department.

For more than two centuries, Pennsylvania public health law has recognized that broad disease control authority should be accompanied by corresponding restraints. Public health and quarantine powers as early as 1818 limited quarantine powers to those which were "most conducive to the public good with the least private injury."[57] The General Assembly carried the same standard into an 1895 law governing cities of the second class, limiting exercise of public health powers such as quarantine to those which circumstances require, and which are "most conducive to the public good with the least private injury."[58] The principle is therefore not foreign to Pennsylvania public health law: broad authority and meaningful restraints can, and historically did, coexist.

Experience during COVID-19 reinforces the importance of that balance. Disease control measures, especially lockdowns, or school mask mandates as expressly contemplated by the Department in these regulations, can impose real and immediate harms, particularly to children.

A 2024 Cochrane review documented a substantial body of empirical literature concerning unintended consequences of COVID-era measures in schools, including immediately apparent harms from masking such as hindered communication.[59] Studies reviewed in that and other systematic reviews identified adverse effects involving speech recognition, language and learning, emotional recognition, social interaction, anxiety, and physical well-being.[60]

[57] Act of Jan. 29, 1818, P.L. 38, No. 30, § 18.
[58] Act of June 26, 1895, P.L. 350, No. 258, § 21.
[59] *Unintended Consequences of Measures Implemented in the School Setting to Contain the COVID-19 Pandemic: A Scoping Review*, Cochrane Database of Systematic Reviews, Issue 4, Art. No. CD015397 (2024), doi:10.1002/14651858.CD015397.pub2.
[60] Johanna Sandlund et al., *Child Mask Mandates for COVID-19: A Systematic Review*, 109 Archives of Disease in Childhood e2 (2024), doi:10.1136/archdischild-2023-326215.

Other literature has documented significant adverse educational outcomes associated with pandemic-era school closures, remote instruction, and related restrictions, including substantial learning loss and widening achievement gaps that have persisted years after schools reopened.[61]

The purpose of examining the pandemic experience is not to relitigate decisions made under conditions of uncertainty, but to learn from them. The fact that officials acted in response to a public health threat does not mean that every intervention chosen was ultimately shown to be necessary, proportionate, or free of consequential harm. A regulatory scheme written after that experience should incorporate the lessons revealed in its aftermath rather than respond to the limitations identified in *Corman* by enlarging the same discretion without adding corresponding restraints.

At an absolute minimum, measures of the kind contemplated by this regulation should expressly be subject to applicable constitutional and statutory limitations and should require that any measure burdening individual liberty or other protected interests be reasonably related to a defined public health threat, supported by the circumstances then existing, no broader or longer than necessary to address that threat, and implemented through the least intrusive and minimally invasive reasonably available means. Investigative and other compulsory authority should likewise be expressly limited to the persons, premises, things, and records reasonably related to the disease, condition, or public health threat giving rise to the exercise of authority.

The regulation itself must provide meaningful standards governing what may be done, to whom, under what circumstances, for how long, and subject to what protections. The Act's requirements concerning clarity, reasonableness, statutory authority, and policy decisions of such a substantial nature that legislative review is warranted are particularly implicated by a regulation of this breadth.

Constraints on exercise of intrusive powers, even if exercised in the name of public health, are appropriate. The proposed rulemaking should not respond to the limitations identified in *Corman* simply by removing them.

Accordingly, the Department should withdraw or substantially revise proposed § 27.60 to restore meaningful limits upon the extraordinary authority it claims. Absent such revision, the provision cannot be found consistent with the statutory authority and intent of the General Assembly or in the public interest under the Act. Its breadth, lack of meaningful limiting standards, intrusion upon constitutionally and statutorily protected interests, and authorization of substantial policy choices without adequate legislative direction implicate the Act's criteria concerning statutory authority, clarity, reasonableness and necessity, protection of the public health, safety and welfare, and policy decisions of such a substantial nature that legislative review is warranted.

<u>§ 27.60a. Investigation of cases, outbreaks, public health emergencies and unusual occurrences of diseases, infections, and conditions.</u>

[61] Maciej Jakubowski, Tomasz Gajderowicz & Harry Anthony Patrinos, *COVID-19, School Closures, and Student Learning Outcomes: New Global Evidence from PISA*, 10 *npj Science of Learning* 5 (2025), doi:10.1038/s41539-025-00297-3.

Proposed § 27.60a would authorize the Department or a local health authority to investigate any case, outbreak, public health emergency, or unusual occurrence involving a disease, infection, or condition. For that purpose, an authorized representative could enter an apartment, building, health care facility, school, college or university, or any "other location" deemed necessary, and no person could obstruct or interfere with the investigation.

These proposed provisions raise concerns related to those articulated in § 27.60. An investigation does not exist outside ordinary constitutional limitations merely because its purpose is public health. Authority to investigate is not synonymous with authority to enter any place, inspect any premises, or obtain any record upon presentation of governmental identification and over the objection of the person possessing the premises or information.

The Fourth Amendment of the U.S. Constitution and Article I, Section 8 of the Pennsylvania Constitution protect against unreasonable governmental searches, including administrative inspections. In *Camara v. Municipal Court*, the United States Supreme Court rejected the proposition that the government's legitimate interest in conducting health and safety inspections categorically eliminates the warrant requirement. The Court recognized the importance of municipal health and safety inspections while holding that, absent consent or an applicable exception, an occupant generally may insist that governmental inspectors obtain lawful process before entering private premises.[62]

Presentation of Department identification establishes who the investigator is; it does not establish a legal entitlement to enter private property. Nor can a regulation make an otherwise protected search constitutionally reasonable merely by declaring that no person may interfere with it. Consent, an appropriately issued warrant or administrative order, exigent circumstances, or another recognized source of lawful authority ordinarily supplies the legal basis for governmental entry where constitutional protections attach.

That ambiguity is magnified by the enforcement consequences discussed above. A person who refuses entry, withholds records, or insists that the Department obtain lawful process could face criminal prosecution if that conduct is characterized as obstruction or interference. A regulation carrying those consequences must clearly distinguish unlawful interference from the good-faith assertion of constitutional or statutory rights.

The regulation should expressly distinguish between entry or inspection by consent and compulsory entry or inspection. Where consent is withheld, it should require the Department to obtain a warrant, administrative order, or other process required by applicable law. Nothing in the regulation should suggest that presentation of identification alone extinguishes the right to refuse warrantless entry or that exercising a constitutional right to insist upon lawful process constitutes unlawful interference with the Department.

Public health investigations can involve urgent circumstances in which delay presents a genuine threat to life or permits communicable disease to spread. The law already accommodates such circumstances through recognized emergency and exigency principles. What it does not require is treating every public health investigation as an emergency, every premises as freely

[62] *Camara v. Municipal Court*, 387 U.S. 523 (1967).

searchable, or every assertion of Department authority as self-validating. The regulation should preserve the distinction.

The predicate for exercising these investigative powers should also be defined with greater precision. The more intrusive the investigative authority asserted, the more important it becomes that its exercise be tied to an identifiable disease, condition, exposure, or other defined public health threat and supported by an articulable public health basis. Broadly defined terms should not permit compulsory investigative authority to be invoked merely because an occurrence can be characterized as health-related. Taken literally, a complaint that an occupant developed headaches or eye irritation attributed to a household product or light bulb could be characterized as a case or "unusual occurrence" of a broadly defined "condition" and become the asserted predicate for entering an apartment, school, or house of worship. The regulation should require a reasonable nexus between the subject and scope of the investigation and the particular public health threat giving rise to it.

These deficiencies weigh directly against a finding that proposed § 27.60a is in the public interest under the Act. A regulation authorizing intrusive governmental investigations must provide clarity concerning the scope of the authority conferred, operate within the Department's statutory authority, be reasonable and necessary to accomplish its legitimate public health purpose, and adequately protect the public welfare, including constitutional rights. As presently drafted, § 27.60a does not provide those safeguards. The Department should substantially revise the provision to distinguish consensual from compulsory access, and preserve the right to insist upon lawful process. If those deficiencies are not corrected in the final-form regulation, the Commission should disapprove the provision.

§ 27.60b. Contact tracing and partner services, generally.

Proposed § 27.60b raises related concerns by carrying the expanse of the preceding investigative authority into private and institutional settings. The provision authorizes Department and local health officials to enter apartments, buildings, health care facilities, schools, colleges, universities, or other locations as those officials deem necessary to conduct contact tracing or partner services, and separately provides that a person "may not obstruct or interfere" with those activities.

Taken together with proposed § 27.60a and the expansive definitions discussed above, the provision appears to permit (1) a broadly defined disease, infection, "condition," or "unusual occurrence" to trigger an investigation; (2) that such investigations provide the predicate for entry into a virtually unlimited range of locations (including a private residence or house of worship); (3) that entry may be undertaken for purposes as broad as "partner services"—including education or referral concerning reproductive health, prenatal care, substance use treatment, housing assistance, legal services, mental health services, and other matters; and (4) that no person, including the person sought for investigation, may obstruct or interfere with those activities. This provision is particularly ominous when viewed against the landscape of potential fines and prosecution as provided for under the DPCL, not only for individual rights, but for parental consent in the case of minors, which will be further discussed below. It is also out of step with the CDC's own recommendations that "[p]articipating in partner services should be

voluntary for both infected persons and their partners; they should not be coerced into participation."[63]

No such extraordinary chain of authority could reasonably be contemplated within the scope of enabling statutes such as the DPCL, or withstand any reasonable scrutiny under the Act's public interest criteria.

Most immediately, § 27.60b inherits the concerns discussed above regarding governmental entry onto private property. The regulation does not distinguish consensual access from compulsory entry, or acknowledge the constitutional protections that may attach to particular premises or activities. Rights against unreasonable search and seizure do not disappear because the government official seeking entry acts in the name of public health rather than law enforcement. Nor can the prohibition against obstruction or interference convert an otherwise protected refusal of entry into unlawful conduct.

The proposed use of such powers for contact tracing does not lessen those concerns. It is understood that contact tracing may serve legitimate disease control functions. Its exercise, however, should remain tied to an identified communicable disease or other defined public health threat and to persons reasonably believed to have been infected, exposed, or otherwise epidemiologically connected to that threat. Access to premises and individuals should likewise be reasonably necessary to the investigation, limited in scope and duration, and conducted through the least intrusive reasonably available means. Where entry implicates constitutional protections, the traditional requirements of consent, a warrant or other lawful process, or a recognized exception to the warrant requirement continue to apply. The public health purpose of an investigation does not itself create an exception to those protections.

The expansive definition of "partner services" further reinforces the concerns identified above regarding elastic terms like "condition," "health-related event," and "unusual occurrence." By sweeping education and referrals for housing, legal, social, and unspecified "other services" into compulsory disease control authority, the Department illustrates how virtually any matter can be characterized as health-related and brought within its asserted powers. These ancillary services extend materially beyond preventing transmission, treating the disease under investigation, or addressing its direct consequences. The DPCL's authority to investigate and control disease does not authorize the Department to compel access to an individual for such purposes merely because that person first came to the Department's attention through a disease investigation.

For these reasons, proposed § 27.60b does not conform to the public interest criteria of the Act. Its breadth raises substantial questions concerning statutory authority, reasonableness and necessity, clarity and lack of ambiguity, and the protection of constitutional rights, while less intrusive means are readily available to accomplish legitimate disease control objectives.

<u>§ 27.60c. Contact tracing and partner services in schools.</u>

[63] Centers for Disease Control and Prevention, *Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection*, 57 MMWR Recommendations and Reports No. RR-9 (Nov. 7, 2008), PMID: 18987617.

Proposed § 27.60c extends into educational settings substantially similar authority already conferred by proposed § 27.60b. The redundancy is itself notable. Section 27.60b proposes newly authorize the Department or a local health authority, during an investigation, to enter a school or other location as necessary to conduct contact tracing or partner services. Section 27.60c compounds the issue by separately imposing affirmative duties upon schools and school personnel to facilitate "reasonable and timely access" to students and other persons, including while classes are in session or whenever the person is present on school premises or attending a school function, and requires school employees and officials to permit Department personnel to meet and speak with a student or other person "in private." School personnel would be prohibited from interfering with a minor's exercise of rights under 35 P.S. § 10103 and, like any other person, from obstructing or interfering with the Department's activities. This in itself is a stunning overreach of authority that completely excludes parental consent.

In sum, the regulation would conscript school personnel into locating students and other persons, interrupting and removing them from their ordinary school activities, producing them for confined, quasi-custodial interviews with government health officials about a host of deeply personal topics, and refraining from interference, all under apparent threat of criminal penalties. Once again, no legislative grant of authority could possibly be invoked to justify such extraordinary powers, or plausibly satisfy public interest standards.

The extent of the authorized interviews warrants particular attention. Though proposed § 27.60c contemplates students, it is not limited to them. It applies to any "person" present at school or attending school functions, including employees or volunteers, as well as parents, family, or neighbors who might be spectators at athletic events, attendees at school performances, or participants at off-site school events such as field trips. The regulation does not limit a private interview to notification of a defined exposure, identification of a communicable disease, or another particularized disease control purpose. And it authorizes such access for purposes of "partner services" which, as noted above, encompasses a "broad array" of services such as health education and referrals involving reproductive health, prenatal care, substance use treatment, mental health services, housing assistance, legal services, social services, and unspecified "other services." Indeed, the open-endedness of this definition establishes virtually no subject matter boundaries governing what may be discussed privately with a child or adult. Mental health and other services plausibly include highly sensitive matters involving sexuality, gender identity, family relationships, and personal behavior.

By referencing 35 P.S. § 10103, the Department clearly telegraphs that these conversations are intended not merely to gather information or notify a student of a defined exposure, but to produce treatment-related decisions. That statute permits a minor to consent to medical and health services to determine the presence of or treat pregnancy, venereal disease, and any other reportable disease. In context, the resulting referrals could lead to pregnancy-related services, testing, and antibiotic treatment for chlamydia, gonorrhea, or syphilis, antiviral treatment for HIV or hepatitis, vaccination or post-exposure prophylaxis, and treatment for reportable conditions ranging from tuberculosis and mpox to chickenpox, cat-scratch fever, giardiasis, and Pontiac fever, among the Department's many other newly proposed additions. Against that extraordinarily broad backdrop, the regulation permits private conversations calculated to

produce medical counseling, referrals, testing, prophylaxis, or treatment while providing no parental notice or consent, and no meaningful limitation upon the subjects that may be discussed.

The absence of parental notice or consent is especially anomalous when compared with the Department's own rules for ordinary school health care. Pennsylvania regulations require school entities to establish medication-administration policies and procedures under Department guidelines.[64] Those guidelines state that, except for medications administered under a standing order during a life-threatening emergency, "all medications given in the school setting must have a written authorization (consent) from a parent/guardian."[65] This requirement extends even to over-the-counter medications such as acetaminophen or antacids, which must be treated as prescribed medications requiring both a licensed prescriber's order and parental consent. Thus, under the Department's existing framework, a school nurse generally may not give a child Tylenol without written parental authorization, yet proposed § 27.60c would facilitate private governmental conversations and treatment referrals concerning pregnancy, sexually transmitted infections, and a greatly expanded universe of reportable diseases without requiring that the parent even be notified.

The Department partly justifies private, compulsory access to minors as helping Pennsylvania compete with other states, while acknowledging that the regulations of those states contain no comparable provision. Economic or institutional competitiveness does not establish statutory authority or explain why government officials require compulsory, private access to children for this open-ended range of services.

The coercive effect upon teachers and school officials is unmistakable. Proposed § 27.60c imposes affirmative duties to provide "reasonable and timely access," permit private interviews, and refrain from obstruction or interference. Because violations may be prosecuted as summary offenses, a teacher, principal, administrator, or other school employee who declines, delays, or conditions a request while seeking legal or administrative guidance could face criminal prosecution, fines, and potentially imprisonment. Prosecutions may be instituted not only by the Department or a local health authority, but by "any person having knowledge of a violation."[66] Those consequences are particularly indefensible where the regulation does not adequately define what access is "reasonable," what response is "timely," or what conduct constitutes prohibited interference. And, as with medical professionals, criminal charges could also carry professional consequences (including forfeit of teaching certificates) in an era where schools continue to grapple with teacher shortages.

Parents face an equally serious threat. The prohibition against obstruction or interference applies to any "person" and contains no express exception or safe harbor for a parent who objects to a private governmental interview, requests notice, insists upon being present, questions whether the proposed discussion bears a reasonable relationship to communicable-disease control, or invokes constitutional or statutory rights concerning the care and upbringing of the child. Read

[64] 22 Pa. Code § 12.41(a).
[65] Pennsylvania Department of Health, *Guidelines for Pennsylvania Schools for the Administration of Medications and Emergency Care* §§ VII.B–D (June 21, 2010).
[66] 35 P.S. § 521.20(a)-(b).

literally, such conduct could potentially be characterized as interference and expose the parent to the DPCL's criminal penalties.

This is perilous and unconscionable territory. The proposed regulation is not merely overbroad or insufficiently explained. In its present form, it constitutes an unacceptable intrusion upon the parent-child relationship. A regulation carrying criminal consequences should not leave parents and educators to guess whether asserting a constitutional right, requesting legal process, or declining governmental access constitutes unlawful obstruction.

Federal and Pennsylvania jurisprudence make clear that parents possess substantial and primary constitutional authority over the care, custody, upbringing, education, and medical treatment of their minor children. The United States Supreme Court has repeatedly recognized the protected role of parents in directing a child's upbringing and education and has described parental decision-making concerning care, custody, and control as a fundamental liberty interest.[67] The protection extends to medical decision-making, as the Court has established that children themselves possess liberty interests against unnecessary governmental restraint undertaken for health purposes, and rejected the premise that government officials may substitute their judgment for that of the parent, holding that parents retain a "substantial, if not the dominant, role" in decisions concerning their child's medical care (absent a finding of neglect or abuse).[68]

The Third Circuit has applied these constitutional principles directly within the public-school setting. In *Gruenke v. Seip*, the court warned that "[p]ublic schools must not forget that 'in loco parentis' does not mean 'displace parents'" and that "[i]t is not educators, but parents who have primary rights in the upbringing of children." It specifically recognized that school-sponsored counseling and testing that pry into private family activities "can overstep the boundaries of school authority and impermissibly usurp the fundamental rights of parents to bring up their children." The court further established that compelled diagnostic testing by government officials may constitute a governmental search and implicate a student's constitutional privacy interest in sensitive medical information. School officials who cross these constitutional boundaries cannot necessarily rely upon qualified immunity to shield them from personal liability.[69]

Pennsylvania law is equally unambiguous. In *Hiller v. Fausey*, the Pennsylvania Supreme Court recognized parental control over the care, custody, and upbringing of children as a fundamental right and subjected governmental infringement of that right to strict scrutiny.[70] The Commonwealth Court similarly outlined the "time-honored" principle that parental consent must precede medical treatment for minors, and that generally, "it is for the parent in the first instance to decide what is actually necessary for the protection and preservation of the life of his or her child."[71] While exceptions to these principles exist, they are specific and limited. A statute giving a minor legal capacity to consent to specified medical services does not inherently impose parental exclusion or secrecy, nor does it abolish underlying parental rights, nor is it a grant of

[67] *Pierce v. Society of Sisters*, 268 U.S. 510 (1925); *Wisconsin v. Yoder*, 406 U.S. 205 (1972); *Troxel v. Granville*, 530 U.S. 57 (2000).
[68] *Parham v. J. R.*, 442 U.S. 584, 99 S. Ct. 2493, 61 L. Ed. 2d 101 (1979).
[69] *Gruenke v. Seip*, 225 F.3d 290 (3d Cir. 2000).
[70] *Hiller v. Fausey*, 588 Pa. 342, 904 A.2d 875, 877 (2006).
[71] *Parents United for Better Schs., Inc. v. Sch. Dist. of Philadelphia Bd. of Educ.*, 166 Pa. Cmwlth. 462, 646 A.2d 689, 692 (1994).

plenary authority for the Department to obtain private access to that minor for any health, social, legal, or other service encompassed within its newly defined "broad array" of partner services.

Pennsylvania's school health laws (which the Department cites to in part when discussing immunizations) reinforce the same structure. The Public School Code requires that parents or guardians be advised in advance of, and urged to be present for, school medical examinations (including those required by the Secretary of Health), and further provides that "[m]edical examinations shall be made in the presence of the parent or guardian of the child when so requested by the parent or guardian."[72] Thus, even where the Commonwealth has expressly authorized school-based health examinations, Pennsylvania law preserves parental notice and, upon request, parental presence. Parents or guardians further have the express right to opt out of such medical examinations or treatments on religious grounds, excepting only in cases where the Secretary of Health finds facts establishing that the exemption constitutes a "present substantial menace" to the health of others.[73] This prerogative for opting out is so fundamental that it extends even to the emergency administration of epinephrine.[74]

While school cooperation with local health officials is permitted under the School Code, it is not required.[75] Furthermore, while the Secretary of Health has authority to examine school buildings and grounds,[76] and jurisdiction to approve school physicians, standards, and duties, administration and supervision of the educational and teaching aspects of school health programs is reserved for the Secretary of Education.[77]

Of further concern are the qualifications and clearances for government health officials conducting such sequestered interviews with students. The School Code requires employees and contractors having direct contact with children to obtain specific background checks and clearances, including Pennsylvania State Police, child abuse histories, and FBI criminal history checks.[78] ("Direct contact with children" includes the possibility of care, supervision, guidance or control of children, or routine interaction with them.[79]) Complementary requirements also exist under the Child Protective Services Law.[80]

Proposed § 27.60c contains no comparable framework. It would require schools and their personnel to facilitate private access by outside government personnel to individual students while saying nothing about parental notice or presence, applicable child protection clearances, supervision, religious objections, opt-out rights, or other safeguards governing such encounters. (That concern cannot readily be avoided by characterizing Department personnel as "official visitors," as the term plainly contemplates high-ranking, mostly elected officials such as the

[72] 24 P.S. §§ 14-1404, 14-1405.
[73] 24 P.S. § 14-1419.
[74] 24 P.S. § 14-1414.2(g).
[75] 24 P.S. § 14-1411.
[76] 24 P.S. § 14-1420.
[77] 24 P.S. § 14-1421.
[78] 24 P.S. § 1-111.
[79] 24 P.S. § 1-111.1.
[80] 23 Pa.C.S. §§ 6344, 6344.2.

Governor, Lieutenant Governor, members of the General Assembly, the Secretary of Education, and members of the State Board of Education.[81])

To reiterate, these omissions are particularly disturbing given the breadth of proposed "partner services," discussed earlier, and the truly unprecedented intrusion they represent into parental decisions concerning the care, treatment, and upbringing of children.

Compulsory school attendance does not transfer the parent's fundamental constitutional role to school or health officials or provide an independent avenue around parental rights. Most recently, in *Mahmoud v. Taylor*, the Supreme Court reaffirmed those rights in the public school setting, requiring an appropriate opt-out where school practices substantially burdened parents' right to direct their children's religious upbringing.[82] That principle is particularly significant where "partner services" may involve private governmental conversations with children concerning sexuality, reproductive health, pregnancy, family relationships, or other matters implicating sincerely held religious beliefs.

The problem, then, is not whether the Department may conduct certain legitimate disease investigations within the scope of its delegated authority, or whether minors may exercise rights expressly and narrowly conferred by law. It is whether those limited authorities justify a regulation that compels schools to produce children for private governmental interviews, threatens educators and potentially parents with penalties for "interference," provides no defined standard for parental notice or participation, and extends beyond disease investigation into a broad range of medical, social, legal, and family-related subjects.

Proposed § 27.60c presents substantial concerns under the Act regarding redundancy, clarity and ambiguity, necessity, reasonableness, protection of public health and welfare, and whether it embodies a policy decision of such substantial nature that legislative involvement is warranted. The Department should withdraw this section, and if not, IRRC should disapprove the regulation as inconsistent with the public interest.

§ 27.60d. Partner services relating to HIV, AIDS and other sexually transmitted and related diseases.

Proposed § 27.60d expands an existing HIV-specific notification requirement into a broader affirmative duty applicable to a health care practitioner or other person providing sexually transmitted disease, HIV, or "related" test results. The provider must inform the patient that the Department or local health authority may contact the patient for a "voluntary confidential interview" concerning partner services. As with other affirmative duties imposed by Chapter 27, failure to comply potentially carries the penalties prescribed by the DPCL.

The provision therefore compels a health care provider or other regulated person, on pain of legal penalty, to deliver a government-prescribed message to a patient. The Department itself explains the purpose of the mandate. Patients may be surprised or unwilling to discuss intimate health issues with government officials. This mistrust, the Department suggests, may be overcome by taking advantage of the trust built up between a patient and their doctor or other provider.

[81] 24 P.S. §§ 1-110, 1-102.
[82] *Mahmoud v. Taylor*, 606 U.S. 522, 145 S. Ct. 2332, 222 L. Ed. 2d 695 (2025).

Requiring the provider to prime the patient for government outreach extends the provider's earned goodwill and trust to government officials, lowering resistance to discussion of the vast array of services identified under "partner services."

Notably, § 27.60d expressly describes the contemplated Department interview as "voluntary." The concept is a welcome one, but its inclusion here draws sharp contrast to its conspicuous absence in other provisions (such as § 27.60b and § 27.60c) which instead require access, private interviews, and noninterference. If partner services interviews are voluntary under § 27.60d, the regulation should extend that concept equally throughout its text, including making clear that neither a patient nor a minor is compelled to participate in partner services and that declining or terminating an interview, or requesting parental or other lawful assistance, does not constitute obstruction or interference.

VII. EXCLUSION, READMISSION, AND IMMUNIZATION REQUIREMENTS

§ 27.72. Exclusion based upon symptoms.

The symptom-based exclusions proposed in 27.72 raise a different concern. Several identified symptoms are nonspecific and may occur for reasons wholly unrelated to communicable disease. Most notably, the Department proposes exclusion for "diarrhea generally," unless attributable to a disease or condition governed by the specific requirements of § 27.71a. Whether the intent is reasonable, the practical outcome seems to be exclusion of anyone, child or adult, experiencing diarrhea, regardless of whether it derives from an infectious disease, a medication, or simply an ill-advised lunch, until the person obtains medical clearance to return. (This, despite the Department simultaneously explaining its removal of "persistent diarrhea" elsewhere on the ground that persistence is subjective and diarrhea may result from medication side effects and other conditions that do not warrant exclusion.) The proposal should distinguish symptoms reasonably suggestive of infectious disease from ordinary or transient symptoms having no demonstrated communicable cause.

Likewise, any person in charge of a school, college, university or childcare group setting must exclude a person exhibiting a temperature of 100.4 °F or higher—a reduction of 1.6 °F from the current regulatory requirement of 102 °F. An elevated temperature is a significant, but nonspecific clinical finding that may have noninfectious causes such as an ear infection. A transient elevation may result from recent physical exertion, environmental heat exposure, measurement technique or equipment errors, and, standing alone, may not establish that an individual has or is transmitting a communicable disease.

Because these are mandatory determinations made within the enforcement structure of Chapter 27, and a failure to exclude may potentially expose the responsible person or institution to the DPCL's penalties, the regulation must provide objective and clinically coherent standards, particularly where the identified symptom is nonspecific and may have an entirely noninfectious cause.

§ 27.77. Immunization requirements for children in childcare group settings.

Proposed subsection (b.1) recognizes natural immunity where a health care practitioner determines that a child possesses sufficient antibody levels, and the regulation accordingly

replaces the narrower concept of "vaccination requirements" with "immunity requirements." Recognition of naturally acquired immunity is particularly appropriate in a regulation whose legitimate public health concern is whether a person is susceptible to infection, rather than the particular means by which immunity was acquired—a recognition that has often been lacking in recent years.

The proposal also appropriately preserves religious objections and expressly recognizes a written objection based upon a strong moral or ethical conviction similar to a religious belief, consistent with existing Pennsylvania school immunization regulations. These protections should be retained in the final-form regulation.

VIII. SEXUALLY TRANSMITTED DISEASES AND GENDERED LANGUAGE

§ 27.89. Examinations for syphilis.

The Department proposes in various provisions, including §§ 27.1, 27.89, 27.98, and 27.99, to replace existing sex-specific language concerning pregnancy, childbirth and postpartum conditions with sex-neutral terminology. Among other changes, "pregnant woman" becomes "pregnant individual," "mother of newborn" becomes "postpartum individual," and "mother of stillborn" becomes "case of stillbirth." The Department tersely describes such revisions as an effort "to utilize current terminology" and to pursue "gender neutrality."

That explanation is hardly adequate. Nowhere does the Department cite scientific authority establishing that terms such as "pregnant woman" or "mother" have become medically inaccurate or obsolete, or suggesting there is a scientific consensus requiring the elimination of accurate sex-specific terminology from medical or public health regulation.

To the contrary, major scientific institutions continue to emphasize that biological sex remains a medically significant variable, not least of all when describing pregnancy and childbirth, and scientifically accurate, clinically appropriate language remains necessary. The National Institutes of Health continues to treat sex as a biological variable essential to precision in terminology, warning that failure to account for sex can undermine the rigor, transparency, and generalizability of scientific findings.[83] The Endocrine Society has advised that sex and gender should not be used interchangeably, that the physiological risks of pregnancy are borne entirely by females, and that biological sex differences in physiology form the foundation for understanding differences in disease, treatment, and health outcomes.[84] An article published in the *Proceedings of the National Academy of Sciences* separates social concepts of gender identity from biological, anatomical, and physiological characteristics, the latter of which are distinctly related to matters of sexual reproduction.[85] Current federal health policy runs directly contrary to the Department's unexplained characterization of sex-neutral pregnancy terminology as simply "current terminology."

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[83] National Institutes of Health, *Consideration of Sex as a Biological Variable in NIH-funded Research*, Notice No. NOT-OD-15-102 (June 9, 2015); National Institutes of Health, Office of Research on Women's Health, *Sex as a Biological Variable* (updated Oct. 17, 2025).

[84] Aditi Bhargava et al., *Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement*, 42 Endocrine Reviews 219 (2021), doi:10.1210/endrev/bnaa034.

[85] Sabra L. Klein et al., *Opinion: Sex Inclusion in Basic Research Drives Discovery*, 112 Proceedings of the National Academy of Sciences (2015), doi:10.1073/pnas.1502843112.

The United States Department of Health and Human Services' current style guide expressly directs federal health communicators to use sex-specific language such as "pregnant women" when writing about pregnancy.[86] That guidance follows Executive Order 14168, which directs federal policy to recognize biological sex.[87]

The Department itself recognizes sex-specific terminology elsewhere in this very rulemaking. In discussing hepatitis A, the Department identifies "men who have sex with men" as a population experiencing distinctly elevated transmission risks. Its HIV testing form expressly records a client's sex as male or female and separately records whether the client has had sexual contact with a male or female. Even the animal bite reporting form attached to the proposal records sex as male or female. The Department therefore continues to identify sex where it considers the distinction epidemiologically useful while selectively eliminating it from provisions concerning pregnancy, childbirth, stillbirth and motherhood.

That distinction is difficult to justify on grounds of scientific precision. Sex does not become less biologically relevant when the subject changes from infectious disease epidemiology to reproduction. Pregnancy is a sex-linked reproductive function, and reproductive anatomy and physiology are directly relevant to the very conditions these provisions regulate. To the extent a patient may be experiencing gender incongruence, nothing prevents a health care practitioner from communicating with that patient accordingly. The choice to eliminate "woman" and "mother" altogether, rather than supplement those terms, is not compelled by science. It is a policy judgment about which categories the Department aspires to codify in regulation.

Moreover, it is a policy judgment that departs from the DPCL, which utilizes sex-based terminology such as woman and mother. The Department may clarify statutory language, but it is not afforded latitude to insert materially different terminology on the strength of mere linguistic preference or adopt a substantive policy judgment that the General Assembly itself did not make.

For these reasons, the Department should retain scientifically accurate sex-specific terminology where sex is directly relevant to the regulated biological condition, particularly in provisions governing pregnancy, childbirth, stillbirth and maternal testing. Wholesale replacement of "woman" and "mother" with sex-neutral terminology is neither scientifically required nor adequately justified in this proposal. Any acknowledgment of gender incongruence can be accomplished through addition rather than subtraction.

§ 27.99a. Prenatal examination for hepatitis C.

The Department separately proposes to expand prenatal testing requirements to hepatitis C and HIV. The Department acknowledges that these requirements will impose additional labor and costs, yet repeatedly states that it lacks sufficient information to quantify them. Instead, it suggests that some costs may be reimbursed by insurance or otherwise borne by patients or

[86] U.S. Department of Health & Human Services, *Web Style Guide*, "Pregnant Women" (last reviewed Aug. 13, 2026).

[87] Exec. Order No. 14,168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, § 2, 90 Fed. Reg. 8615 (Jan. 30, 2025).

practitioners. But shifting a cost from one affected party to another does not eliminate it, nor does the absence of readily available data eliminate the Department's obligation to assess it.

That omission means the question of whether the costs are worth the benefits, and therefore in the public interest, cannot even be reached. The question is not whether the perinatal examinations for hepatitis C or HIV are intrinsically good, but whether the Department has satisfied its obligation under the Act to estimate costs. Manifestly, it has not.

IX. DRAFTING AND TYPOGRAPHICAL ERRORS

The proposed regulatory text contains various facial drafting and cross-reference errors that should be corrected. The definition of "School" contains a stray letter *t* before its citation to 24 P.S. § 13-1327. The definition of "Surveillance" uses the grammatically inconsistent phrase "planning, implementing and evaluation." §§ 27.60a, 27.60b, 27.60c, and 27.60e repeatedly insert commas between "interfere" or "interfere with" and the object of that phrase. More notably, the proposed text of the regulation itself uses the term "contract tracing" three times when "contact tracing" is plainly intended.

The reporting tables contain additional errors, including "*Burkolderia*" instead of "*Burkholderia*," and "*Coxiella burnetti*" instead of "*Coxiella burnetii*." In at least one instance, the tables also omit "the" from "No later than the next work day" in one entry, while terminal punctuation is omitted in others. An erroneous period is placed after "*R. akari*" before the parenthetical Rickettsialpox.

The parenthetical references to § 27.21a in proposed § 27.33a inaccurately describe its subject as "reporting of health care practitioners and health care facilities," omitting that the section concerns reporting "of cases by" those entities. § 27.43a(c) likewise contains a description of § 27.3 ("relating to reporting outbreaks, public health emergencies and unusual diseases, infections and conditions") that does not correspond to the current title (Reporting outbreaks and unusual diseases, infections and conditions).

In its accompanying analysis, the Department additionally cites 12 CFR Part 1271, which governs miscellaneous operations and authorities of the Federal Home Loan Banks. The context plainly indicates that the Department intended to cite 21 CFR Part 1271, governing human cells, tissues, and cellular and tissue-based products.

Individually, some of these errors may appear minor, but collectively they begin to suggest insufficient care and precision in the preparation and review of a regulation that has been years in development and is of extraordinary magnitude and consequence, further undermining confidence in its rigor, completeness, clarity, and accuracy.

X. FISCAL ANALYSIS

While the fiscal impact estimates (or lack thereof) have been elsewhere referenced individually, the cumulative fiscal impact of the proposed rulemaking warrants separate consideration. Viewed collectively, the proposal imposes a profound array of new or expanded reporting, testing,

information-technology, recordkeeping, training, policy development, staffing and compliance obligations upon hospitals, laboratories, health care practitioners, schools, childcare providers and other regulated entities and persons. In numerous instances, however, the Department acknowledges that costs will be incurred while stating that it lacks sufficient information to quantify them.

These unquantified costs are not peripheral to the proposal. They arise from some of its most consequential new requirements. Hospitals and emergency departments will be required to transmit expanded syndromic surveillance information; laboratories and health care practitioners will be subject to substantially expanded disease reporting requirements and accelerated reporting deadlines; providers will incur costs associated with expanded prenatal testing; immunization information will be collected and maintained under revised requirements; and schools, colleges, universities and childcare providers will be required to revise policies and administer expanded exclusion, readmission and immunity requirements. The Department admits these changes will require staff time, equipment and software revisions or acquisition, and changes to laboratory and clinical workflows, recordkeeping, training, policies, and ongoing compliance. Yet, the Department largely treats the asserted absence of information as the end of the analysis rather than the beginning, and unjustifiably translates the absence of data on cost into the absence of cost itself.

The Regulatory Review Act requires the Department to estimate the direct and indirect costs imposed upon the Commonwealth, its political subdivisions and the private sector, as well as additional reporting, recordkeeping, paperwork, legal, consulting and accounting requirements. An administrative shrug is grossly insufficient to meet this requirement. A fiscal analysis that repeatedly acknowledges foreseeable costs but leaves their magnitude unknown deprives the Commission, the standing committees, regulated entities and the public of information necessary to perform that review.

The Department also admits it did not consider less stringent reporting requirements, less stringent reporting schedules or deadlines, consolidation or simplification of reporting requirements, performance standards, or exemptions for affected small businesses as required by the Act. For regulations which significantly expand operational costs and labor, consideration of less burdensome alternatives becomes more important, not less.

Without the Department fulfilling its basic duties under the Act, the Commission cannot adequately determine whether the proposed rulemaking's costs are reasonable, necessary and justified by its anticipated public health benefits. At a time in history where health care and its costs and access are becoming more and more challenging, the fiscal costs, for the most part, do not justify the regulations as proposed.

XI. REGULATORY REVIEW ACT AND CONCLUSION

The Regulatory Review Act was enacted upon the General Assembly's recognition that delegation of legislative authority to administrative agencies must remain subject to meaningful oversight. One of its stated purposes is establishing a process "to curtail excessive regulation and to require the executive branch to justify its exercise of the authority to regulate before imposing

hidden costs upon the economy of Pennsylvania," while preserving ultimate legislative review of administrative regulations.

Consistent with that purpose, the Commission must "first and foremost" determine whether the Department possesses statutory authority to promulgate the regulation and whether the proposal conforms to the intent of the General Assembly. Only thereafter does the inquiry proceed to the broader public interest criteria, including economic and fiscal impacts; protection of the public health, safety and welfare; clarity, feasibility and reasonableness; the need for the regulation; implementation and compliance burdens; whether acceptable data supports the regulation; and whether the proposal embodies policy decisions of such a substantial nature that legislative review is warranted. The principal criteria are addressed below.

1) **Statutory authority and legislative intent.** As discussed throughout this letter, several provisions extend far beyond the prevention and control of communicable and noncommunicable diseases contemplated by the DPCL and related laws. They would create new statewide medical registries, expand mandatory reporting to matters that exceed conventional disease categories, compel access to children for services of impermissibly broad scope without parental notice and consent, authorize entry into private locations, and confer disease control authority reaching persons who are neither infected nor exposed. These are not merely technical updates to an existing statutory program. At minimum, substantial questions remain concerning whether the Department possesses authority to promulgate them and whether they conform to the General Assembly's intent. Under section 5.2(a), those threshold deficiencies alone preclude a finding that the regulation is in the public interest.

2) **Economic and fiscal impacts.** The Department repeatedly acknowledges that practitioners, facilities, laboratories, schools, small businesses, and other regulated entities may need additional personnel, information-technology systems, reporting processes, professional services, and administrative resources, but frequently states that it lacks sufficient information to estimate those costs. It then treats an inability to calculate a known burden as though it established no fiscal impact. The proposed birth defects registry alone could cost taxpayers approximately $8.2 million to $8.5 million over five years if staffing remains near the Department's first-year estimate, exclusive of the unquantified costs imposed upon providers and facilities. The analysis likewise fails to address indirect costs, effects upon productivity, paperwork burdens, potential legal and consulting expenses, or the disproportionate effect of fixed compliance obligations upon independent practices, rural facilities, and other small businesses. The Department therefore has not supplied, or meaningfully attempted to supply, an analysis of sufficient rigor to permit the Commission to determine whether the regulation satisfies section 5.2(b)(1) of the Act. The Department is well aware of the fraught climate among health care professionals and within health care facilities, not least of which because the providers themselves have notified the Department of these challenges. Imposing such burdensome and costly mandates during this challenging climate is indefensible, and will lead to greater reductions in access to care.

3) **Protection of public health, safety, and welfare.** Merely asserting the advancement of public health does not end the public interest inquiry. The Commission must also consider whether the means selected protect the broader public welfare. The proposed regulation

implicates intrusions on bodily autonomy, medical privacy, parental authority, religious exercise, access to education and employment, private property, and the confidentiality of identifiable medical information. It also would also provide the Department with new authority to reimpose measures such as masking children in schools. The Department has not adequately balanced those interests against the asserted benefits or supplied safeguards proportionate to the breadth and coercive effect of the powers claimed. Recent experience demonstrates that even measures adopted for public health purposes can inflict substantial collateral harm when exercised too broadly, too uniformly, or without adequate limiting principles. By addressing intended disease control benefits without conducting a meaningful net benefit analysis of the effects upon children and the broader public, the Department has not demonstrated compliance with section 5.2(b)(2).

4) **Conflict with or duplication of existing statutes or regulations.** The proposed regulation presents various apparent conflicts with, or exceeds the scope of, existing statutes and regulations. Among other concerns, it replaces the DPCL's specific references to "physicians" with the categorically broader term "health care practitioners," while elsewhere substituting narrower, sex-neutral terminology for the statute's express references to pregnant women and mothers. It removes protection for a quarantined person's statutory right to treatment of his or her choice, including treatment by prayer or spiritual means. Its provisions addressing governmental access to schools, private student interviews, parental involvement, and treatment-related referrals are not adequately reconciled with existing school-health laws and regulations governing parental notice and consent, medication administration, religious objections, qualified personnel, and supervision. The proposal also creates potentially duplicative registries, reporting duties, and data-collection systems without adequately accounting for information already collected under existing law. The Department has not identified, reconciled, or adequately analyzed these apparent conflicts and duplications and therefore has not met its burden under section 5.2(b)(3)(i) of the Act.

5) **Clarity and lack of ambiguity.** The proposed regulation repeatedly fails to define the scope of its terms and the limits of the authority it would confer. This includes the expansive definitions identified in Section I, as well as "unusual occurrence," "partner services," "reasonable and timely access," "obstruct or interfere," and the authority to impose "any other" disease control measure. Those ambiguities are particularly consequential because the regulation imposes affirmative duties, authorizes intrusive governmental action, and carries the DPCL's criminal enforcement consequences. Regulated persons should not be required to guess what conduct is mandatory, what conduct is prohibited, or when protected activity may be characterized as interference. The proposal therefore does not satisfy the Act's requirement of clarity and lack of ambiguity under section 5.2(b)(3)(ii).

6) **Need for the regulation.** The Department has not demonstrated the need for several of the proposal's most substantial expansions of governmental authority. It has not shown why every emergency department visit, including one unrelated to a reportable disease or public-health concern, must be transmitted to the Commonwealth; why investigators require authority to enter homes, schools, health care facilities, and virtually any other location upon presentation of identification, without consent or lawful process such as a warrant, for investigations extending to broadly defined "conditions" and "unusual occurrences"; or why

schools must facilitate private governmental interviews for an expansive array of "partner services." It has not identified what material information a new birth defects registry would obtain that is unavailable through newborn screening, vital records, hospital records, Medicaid data, or EDDIE, or why PIERS must be converted from a voluntary immunization registry into a mandatory statewide repository. Nor has it adequately justified more than doubling the number of reportable conditions or authorizing "any other" disease control measure. The Department therefore has not established the necessity of these substantial new mandates and powers as required by section 5.2(b)(3)(iii) of the Act.

7) **Reasonableness of requirements, implementation procedures, and compliance timetables.** The proposal does not establish sufficiently definite or workable procedures for implementing many of its most consequential requirements. Mandates involving reporting, private access to students, entry into broadly-defined locations, production of records, disease control measures, and participation in statewide registries lack adequate limiting standards, notice and consent provisions, lawful-process protections, review mechanisms, and realistic estimates of the personnel and technology necessary for compliance, as well as realistic implementation timelines. The Department's inability to estimate reporting volume and implementation costs further prevents a meaningful assessment of feasibility. The Department therefore has not demonstrated that the proposal's requirements, implementation procedures, and compliance timetables are reasonable as required by section 5.2(b)(3)(iv).

8) **Acceptable supporting data.** The Department has not consistently supplied acceptable data supporting the regulation's most consequential provisions. It has not adequately documented their necessity, expected benefits, likely effectiveness, affected populations, anticipated reporting volume, countervailing interests, secondary effects, or compliance burdens. Indeed, the Department expressly and somewhat unaccountably concedes this fact with an admission in its Regulatory Analysis Form that "The Department did not rely on data as the basis for this regulation." That admission is extraordinary given the breadth of the powers, mandates, and costs proposed. General and at times selective references to national guidance, practices in other states, or the general desirability of improved surveillance cannot substitute for data supporting the particular provisions proposed here. Because the Department acknowledges that the regulation was not based upon data, it cannot establish that acceptable data supports the regulation as independently required by sections 5.2(b)(3)(v) and 5.2(b)(7) of the Act.

9) **Substantial policy decisions requiring legislative review.** The proposal embodies numerous policy decisions of substantial public importance. These include the creation of compulsory statewide medical registries, mandatory reporting of individually identifiable information, governmental access to children for private interviews, entry into homes and other private locations without warrants or other lawful process, and permanent disease control authority extending beyond traditional cases of infection or exposure. Such matters implicate competing constitutional, fiscal, medical, and social interests properly resolved by the General Assembly through clear statutory standards, rather than inferred from generalized administrative authority.

10) **Less costly and less intrusive alternatives for regulations impacting small businesses.** The Department has not demonstrated meaningful consideration of less costly or intrusive

alternatives. As noted above, the Department brushes aside these concerns by asserting all affected entities must submit equally to its mandates, without addressing disparate impacts as required by the Act. A conclusory assertion that no less costly alternative would adequately protect public health is not the analysis the Act requires. The Department therefore has not satisfied its obligation under section 5.2(b)(8) to consider less costly or less intrusive alternatives for regulations affecting small businesses.

Measured against those standards, the defects identified throughout this letter are especially consequential because the challenged provisions would authorize or require compulsory governmental action, entry into private property, access to children and schools, acquisition and centralized retention of identifiable medical information, disease control measures of exceptionally broad scope, impairment or removal of statutory protections for religious exercise and medical choice, reporting and testing mandates, exclusion from schools, employment and childcare, and substantial fiscal burdens that the Department repeatedly acknowledges but frequently declines to quantify.

Pennsylvania has recent experience with the effects of sweeping public health restrictions imposed across entire sectors of society. Businesses closed, restaurants struggled or disappeared, supply chains were disrupted, schools and families were upended, and small businesses absorbed losses from which many took years to recover. Whatever disagreements remain over particular measures adopted during that period, one lesson should be beyond controversy: the distance between a legitimate public health objective and the collateral consequences of governmental action can become enormous when extraordinary authority is exercised too broadly, too uniformly, or without adequate limiting principles.

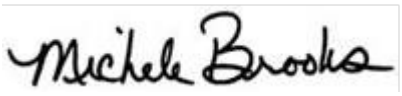
That disconnect cannot be permitted to recur through permanent regulation. Emergency powers should not quietly become ordinary administrative powers. Temporary measures justified by extraordinary circumstances should not be transformed into standing authority untethered from comparable necessity, procedural safeguards, statutory limits, and meaningful legislative oversight. The answer to past uncertainty is not unchecked discretion in the future.

The Department should withdraw the proposed rulemaking and undertake a systematic, comprehensive revision addressing the statutory, constitutional, evidentiary, fiscal, privacy, procedural, and practical deficiencies identified above.

If those deficiencies are not sufficiently addressed before final-form promulgation, the Commission should conclude that the resulting regulation does not satisfy the Regulatory Review Act's requirements concerning statutory authority, legislative intent, clarity, reasonableness, necessity, acceptable data, fiscal impact, protection of the public welfare, and substantial policy decisions warranting legislative review, and should disapprove it.

Thank you for your consideration of these concerns and for your continued service to the Commonwealth.

Sincerely,



Michele Brooks
Chair, Senate Health & Human Services Committee
State Senator, 50th District

Joe Pittman
Senate Majority Leader
State Senator, 41st District

Kim Ward
Senate President Pro Tempore
State Senator, 39th District

Scott Martin
Chair, Senate Appropriations Committee
State Senator, 13th District

David G. Argall
Chair, Senate Majority Policy Committee
State Senator, 29th District

Lisa Baker
Senate Majority Caucus Administrator
State Senator, 20th District

Camera Bartolotta
Senate Majority Caucus Secretary
State Senator, 46th District

Jarrett Coleman
Chair, Senate Intergovernmental Operations Committee
State Senator, 16th District

Lynda Schlegel Culver
Chair, Senate Education Committee
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Cris Dush
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Chair, Senate Finance Committee
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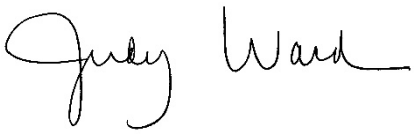
Kristin Phillips-Hill
Senate Majority Caucus Chair
State Senator, 28th District

Greg Rothman
Chair, Senate Game & Fisheries Committee
State Senator, 34th District

Patrick Stefano
Chair, Senate Consumer Protection & Professional Licensure Committee
State Senator, 32nd District

Elder Vogel
Chair, Senate Agriculture & Rural Affairs Committee
State Senator, 47th District



Judy Ward
Chair, Senate Transportation Committee
State Senator, 30th District

Gene Yaw
Chair, Senate Environmental Resources & Energy Committee
State Senator, 23rd District

Wayne Langerholc
Senate Majority Whip
Chair, Aging & Youth Committee
State Senator, 35th District