Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency: HEALTH

(2) Agency Number: 10
Identification Number: 209

IRRC Number: 3235

(3) PA Code Cite: 28 Pa. Code §§ 27.21a, 27.22, 27.23, 27.32a-27.32e

(4) Short Title: Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results relating to HIV

(5) Agency Contacts (List Telephone Number and Email Address):

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

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

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

The Department added HIV infection, a virus that can lead to Acquired Immunodeficiency Syndrome (AIDS) if left untreated, to the list of reportable diseases and conditions in the Commonwealth in 2002. As part of those reporting requirements, the Department required the reporting of CD4 T-lymphocyte test results with a count of less than 200 cells/µL or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes. The Department is now proposing to amend the existing regulations to require the reporting of all CD4 T-lymphocyte cell counts relating to HIV infection, as well as to add the required reporting of all viral load test results and genotyping results relating to HIV. In requiring the reporting of all CD4 T-lymphocyte cell counts, the Department is joining 46 other states that already require all CD4 counts to be reported, and 48 states that require the reporting of all viral load results.

From a societal perspective, the spread of HIV, a virus that can lead to Acquired Immunodeficiency Syndrome (AIDS) if left untreated, is a serious public health issue. By the end of 2018, 36,136 individuals were diagnosed and living with HIV infection in this Commonwealth. 5,565 new HIV cases were diagnosed in the last five years (2014 to the end of 2018), accounting for 15.4% of all of those diagnosed and living with HIV infection by 2018. The estimated number of persons living with HIV has increased each year on average by approximately 1,200 persons. With a growth curve following a very strong linear trend, projections indicate that by 2025, there could be as many as 45,000 individuals in this Commonwealth living with HIV infection.

In order to stop the spread of HIV, prevent the emergence of new cases, and keep those living with HIV healthy, it is necessary to know where and how HIV is spreading. Persons tested for HIV have a recorded CD4 count and viral load, indicators of HIV progression within the body. Because the Department does not currently require the reporting of all CD4 and viral load test results, reporting is incomplete. This severely limits the Department's ability to comply with standards set by the federal Centers for Disease Control and Surveillance (CDC) of the Department of Health and Human Services (HHS), accurately report on CDC-required core HIV indicators, and monitor and enhance patient outcomes across the continuum of HIV care services.

Ultimately, requiring the reporting of all CD4 T-lymphocyte counts, viral loads and genotyping test results would allow the Department to better track the epidemic in the Commonwealth, focus resources to meet the needs of the communities impacted, and improve the health of the citizens of the Commonwealth.

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

The Department's overarching authority to promulgate these regulations is found in the Disease Prevention and Control Law of 1955 ("the act"). 35 P.S. §§ 521.1 – 521.21. Section 16(a) of the act (35 P.S. §521.16(a)) gives the Advisory Health Board the authority to issue rules and regulations on a variety of matters relating to communicable and non-communicable diseases, including the following: the diseases that are to be reported; the methods of reporting diseases; the contents of reports; the health authorities to whom diseases are to be reported; the control measures that are to be taken with respect to different diseases; the enforcement of control measures; the immunization and vaccination of persons and animals; the prevention and control of disease in public and private schools; the treatment of sexually transmitted diseases, including patient counseling; and any other matters the Board may deem advisable to address for the prevention and control of disease and for carrying out the provisions and purposes of the act. Section 16(b) of the act (35 P.S. §521.16(b)) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. § 51 *et seq.*) Section 2102(g) of the Administrative Code (71 P.S. § 532(g)) gives the Department this general authority. Section 2111(b) of the Administrative Code of 1949 (71 P.S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department. Section 2106(a) of the Code (71 P.S. §536(a)) provides the Department with additional authority to declare diseases to be communicable, and to establish regulations for the prevention and control of disease.

Section 2111(b) of the Code (71 P.S. §541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

In addition, Section 803 of the Health Care Facilities Act (35 P.S. §448.803) provides the Department with the authority to promulgate regulations relating to the licensure of health care facilities and allows the Department to require certain actions relating to disease control and prevention to occur within health care facilities.

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

These amendments are not mandated by any federal or state law or court order, or federal regulations, although it should be noted that the Department is one of only three states that have not made all CD4 counts reportable. There are no relevant state or federal court decisions relating to these amendments, however, in order to achieve the goals set out in the *National HIV/AIDS Strategy for the United States, updated for 2020* (July 2015), at Executive Summary 3, https://files.hiv.gov/s3fs-public/nhas-update.pdf. Accessed February 23, 2018 (hereinafter referred to as "*National HIV/AIDS Strategy*"), CDC recommends, among other things, the reporting of all HIV-results (counts and percentages) and all viral load results (both undetectable and specific values). *See Letter from Kenneth G. Castro, M.D., Assistant U.S. Surgeon General, U.S. Public Health Service and Amy Lansky, Ph.D., M.P.H., Deputy Director for Surveillance, Epidemiology and Laboratory Sciences, Division of HIV Prevention, CDC*, a copy of which is attached to the Preamble to this Final Rulemaking as Exhibit "A". A letter directly to the former Secretary of Health, Karen Murphy, from the Director of the Office for State, Tribal, Local and Territorial Support and Deputy Director of the CDC, reiterated this position to the Commonwealth, as one of, at the time of the letter, six states that do not collect all CD4 test results. *See Letter to Secretary Karen Murphy*, dated February 8, 2017, a copy of which is attached to the Preamble to this Final Rulemaking as Exhibit "B". Since that letter was written, two more states have required all CD4 t-lymphocyte test results to be reported. Pennsylvania is now one of only four states that do not collect all CD4 T-lymphocyte test results. *See Email from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health (9/11/2018 10:56 AM),* attached to the Preamble to this Final Rulemaking as part of Exhibit "C". In addition, of the 50 states, only Pennsylvania and Idaho fail to require the reporting of all viral load test results. *See Email from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health (2/28/2018 12:24 PM)*, attached hereto as part of Exhibit "C").

The letter to former Secretary Murphy stated the following:

> The updated National HIV/AIDS Strategy for the United States identifies primary goals to guide our collective national fight against HIV. The success in advancing several of these goals, ensuring sustained viral suppression for person living with HIV and measuring progress towards HIV care, relies on laboratory reporting of HIV-related tests, including all CD4+ T-lymphocyte (CD4) and viral load test results, to local and national HIV surveillance systems. Complete laboratory data are critical to identifying cases, measuring care and treatment outcomes, and measuring the effectiveness of public health interventions. Specifically, these data are often used to monitor disease progression, determine the stage of HIV infection, monitor receipt of HIV care and treatment, and make decisions about public health interventions. Both viral load and CD4 data are used to assess whether patients are responding to treatment: when treatment is successful, CD4 counts rise and viral loads fall. Current HIV clinical management guidelines call for CD4 and viral load testing at the time of diagnosis and regularly thereafter. When CD4 and viral load results are reported, public health agencies can determine access to care and

treatment outcomes. For these reasons, CDC recommends complete state reporting of all HIV test results.

Exhibit "B" (emphasis added).

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

From a societal perspective, the spread of HIV, a virus that can lead to Acquired Immunodeficiency Syndrome (AIDS) if left untreated, is a serious public health issue. By the end of 2018, 36,136 individuals were diagnosed and living with HIV infection in this Commonwealth. 5,565 new HIV cases were diagnosed in the last five years (2014 to the end of 2018), accounting for 15.4% of all of those diagnosed and living with HIV infection by 2018. The estimated number of persons living with HIV has increased each year on average by approximately 1,200 persons. With a growth curve following a very strong linear trend, projections indicate that by 2025, there could be as many as 45,000 individuals in this Commonwealth living with HIV infection.

In order to stop the spread of HIV, prevent the emergence of new cases, and keep those persons living with HIV healthy, it is necessary to know where and how HIV is spreading. Those tested for HIV have a recorded CD4 count and viral load, which test results are indicators of HIV progression within the body. Currently, the Department does not require the reporting of all CD4 and viral load test results. This makes the current information reported incomplete, severely limiting the Department's ability to comply with current CDC standards, accurately report on CDC required core HIV indicators, and monitor and enhance patient outcomes across the continuum of HIV care services. Because the Department does not currently require the reporting of all CD4 and viral load test results, reporting within the Commonwealth is incomplete. This severely limits the Department's ability to comply with standards set by the CDC recommendations, accurately report on CDC-required core HIV indicators, and monitor and enhance patient outcomes across the continuum of HIV care services.

Ultimately, requiring the reporting of all CD4 T-lymphocyte and viral load test results will allow the Department to better track the epidemic in the Commonwealth, focus resources to meet the needs of the communities impacted, and improve the health of the citizens of the Commonwealth. *See National HIV/AIDS Strategy*, at 46. In addition, the Department is more able to ensure that those identified to be infected/living with HIV have access to care, are engaged in care and are virally suppressed. *See, e.g., National HIV/AIDS Strategy*; *see also* Mahle Gray, *et al., Enhanced Collection of Laboratory Data in HIV Surveillance among 5 States with Confidential Name-Based HIV Infection Reporting*, 2005-2006, The Open AIDS Journal, 2012, *6*, (Suppl 1: M5) 90-97, 93-94, 96 ("Data collected through the national HIV surveillance system can be used to monitor the outcomes of the national strategy; however the validity of these measures is dependent upon the completeness and quality of the surveillance data"), attached hereto as Exhibit "D."

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

There are no provisions that are more stringent than federal standards in these amendments. In fact, the CDC and HRSA, which are the Department's federal funding agencies in the area of HIV and AIDS, have continually asked the Department when it intends to make these changes to comport with the goals of the *National HIV/AIDS Strategy*, *see, e.g.*, Exhibit "B," and the reporting required for purposes of the Department's federal grants.

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

At the present time, Pennsylvania is one of only four states in the nation that do not require the reporting of all CD4 test results. *See* Exhibit "C"; *see also* http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-21-4.pdf, at p. 63. Accessed February 23, 2018. In addition, of the 50 states, only Pennsylvania and Idaho fail to require the reporting of all viral load test results. *See* Exhibit "C." Goal 1 of the National HIV/AIDS Strategy, which calls for reducing new HIV infections, *see National HIV/AIDS Strategy* at 1, sets forth as a recommended action the allocation of public funding consistent with the geographic distribution of the epidemic. *Id.* at 19. The Strategy recommends a similar action with regard to Goal 4, achieving a more coordinated national response to the HIV epidemic. *Id.* at 43; *see also* 45 ("The Federal government should review the methods used to distribute Federal HIV funds and take steps to ensure that resources go to the States and localities with the greatest burden of disease.") If, in the future, federal funding is tied to disease burden, the Commonwealth would be at a disadvantage among other states with more complete data. The letter sent to Dr. Murphy in 2017 notes that other states, with complete reporting, are better able to monitor their success, have increased reporting, have more accurate and more timely HIV surveillance data, and are using the data to inform public health action. *See* Exhibit "B." Failure to update the Department's regulations will place the Commonwealth at a disadvantage against these other states.

Ultimately, requiring the reporting of all CD4 T-lymphocyte and viral load test results will allow the Department to better track the epidemic in the Commonwealth, focus resources to meet the needs of the communities impacted, and improve the health of the citizens of the Commonwealth. *See National HIV/AIDS Strategy*, at 46. In addition, the Department is better able to ensure that those identified to be infected/living with HIV have access to care, are engaged in care and are virally suppressed. *See, e.g., National HIV/AIDS Strategy*; *see also* Exhibit D, at 96 ("Data collected through the national HIV surveillance system can be used to monitor the outcomes of the national strategy; however the validity of these measures is dependent upon the completeness and quality of the surveillance data.")

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

The amendments will not affect the regulations of any other state agency. The Department is currently proposing to revise other parts of the regulations relating to communicable and noncommunicable diseases (28 Pa. Code Ch. 27), but this rulemaking will complement those revisions.

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

The Department held a meeting of the Advisory Health Board to review and approve the proposed regulations on two occasions, July 25, 2018 and September 18, 2018. Both meetings were public meetings at which the Department presented the proposed regulations to the Board for its review and approval. The Department published notice of the July meeting in the *Pennsylvania Bulletin* on July 21, 2018 (48 Pa.B. 4354 (July 21, 2018)), and of the September meeting on September 15, 2018 (48 Pa.B. 5805 (September 15, 2018)), in advance of the meetings, and in accordance with the requirements of the Sunshine Law. The Board voted on September 18, 2018 to approve the proposed regulations.

The Department published proposed rulemaking in the *Pennsylvania Bulletin* on May 25, 2019 (49 Pa.B. 2605 (May 25, 2019) and provided a 30-day public comment period. The Department accepted comments until a week following the close of the public comment period. The Department received comments from four commentators, three in support, and one opposed. The Department reviewed the comments, made some changes, and responded to all comments in the Preamble to this final rulemaking.

The Department again convened the Advisory Health Board to review the final rulemaking on January 14,2020. The Department presented the final amendments to the Board for its review and approval. The Department published notice of the January meeting in the *Pennsylvania Bulletin* on December 21, 2019 (49 Pa.B. 7505 (December 21, 2019)) in advance of the meeting, and in accordance with the requirements of the Sunshine Law. The Board voted on January 14, 2020, to approve the final rulemaking.

The Department also provides requested updates to the Statewide HIV Planning Group (HPG) relating to the Department's activities relating to HIV prevention and planning. The HPG is established by Department under Sections 301(a) and 317 of the Public Health Service Act (42 U.S.C.A. §§ 241(a) and 247b), and provides input on jurisdictional HIV prevention planning, a required activity of the Department's Centers for Disease Control and Prevention (CDC) grant for Comprehensive HIV Prevention Programs for Health Department. The HPG also fulfils the requirement under the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. Law 111-87), previously known as the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (42 U.S.C.A. §§ 300ff-21 – 300ff-38), that the Department engage in a public advisory planning process in developing a comprehensive plan. The HPG sent a letter in support of CD4 and viral load reporting in regard to DOH's proposed regulations in 2016, *see Letter from HIV Planning Group*, dated December 21, 2016 (attached hereto as Exhibit "E").

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

All healthcare practitioners, healthcare facilities and laboratories statewide, and all persons who make diagnoses of HIV or AIDS or who receive or provide HIV test results and CD4 T-lymphocyte test results were required to comply with the regulations relating to the reporting of AIDS and HIV disease, including specified CD4 T-lymphocyte test results promulgated in 2002. These same types of providers, facilities and laboratories would be required to comply with these amendments to the disease reporting requirements relating to HIV.

The Department reviewed relevant Small Business Size Standards in 13 CFR Chapter 1, Section 121.201 (http://www.gpo.gov/fdsys/pkg/CFR-2011-title13-vol1/pdf/CFR-2011-title13-vol1-sec121-201.pdf), specifically Sector 62 – Health Care and Social Assistance. The Department identified categories of health care providers and clinics that are likely to diagnose diseases required to be reported. Additionally, the Department obtained small business information from the state Department of Labor and Industry. Based on those data, the Department determined an estimate of the number of businesses in the Offices of Physicians category (621,111), and Medical Laboratories (621,511) that qualify as small businesses (<50 employees).

These small businesses are currently mandated disease reporters and would continue to be mandated disease reporters under the proposed amendments. Mandated disease reporters are required to report to the Department's internet based electronic disease surveillance system (PA-NEDSS) all cases of diseases listed as reportable in 28 Pa. Code §§ 27.21a (relating to reporting of cases by health care practitioners and health care facilities) and 27.22 (relating to reporting of cases by clinical laboratories) of the current regulations. The current reporting regulations require the reporting of positive HIV tests and CD4 T-lymphocyte test results equal to or less than 200, and that are more than 14% of total T-lymphocyte cells. The proposed amendments would expand this reporting requirement to require reporting of all CD4 T-lymphocyte test results, rather than some of those results, and would require the reporting of all viral load test results, even those with a non-detectable viral load. The amendments would also require the reporting of HIV genotyping test results.

The impact of the proposed amendments should be minimal. Healthcare practitioners and clinical laboratories currently are required to have systems in place to report some CD4 and HIV viral load test results into PA-NEDSS, so although the proposed amendments would result in reporting of all CD4 and HIV viral load results and genotyping test results, these reporters would not need to develop new systems. Currently, healthcare practitioners and clinical laboratories have to separate CD4 and viral load test results to eliminate those that are not reportable under the current regulations, and this process takes time and adds cost. The proposed amendment would require them to report all the test results and remove the need to separate the results before reporting; thereby saving them time from separating the test results. Healthcare practitioners and laboratories without the ability to send data electronically directly to PA-NEDSS would be required to keystroke enter these additional test results into PA-NEDSS. However, most CD4 and HIV viral load information is received from clinical laboratories with IT systems allowing direct electronic access and data upload. For these facilities, once their IT system is modified to capture the additional test results, the data would be automatically extracted and uploaded to PA-NEDSS, so there would be no ongoing cost associated with the additional reporting requirements.

All persons affected by or infected with HIV/AIDS are impacted by these amendments. All Pennsylvanians would benefit from this final rulemaking through the Department's improved ability to

track of trends in HIV infection and treatment success, as well as assisting patients with linkage to care and treatment before they develop significant and expensive medical complications. These amendments will help to protect Commonwealth citizens from exposure to HIV and subsequent hardship, disability, or death. In addition, it will enable the Commonwealth to comply with CDC recommendations for effective HIV disease surveillance, control and patient management.

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

Healthcare practitioners, healthcare facilities and laboratories statewide, and persons who make diagnoses of HIV or AIDS or who receive or provide HIV test, CD4 T-lymphocyte test results were required to comply with the previous regulations relating to the reporting of AIDS and HIV disease, including specified CD4 T-lymphocyte test results. These same providers, facilities and laboratories will be required to comply with these amendments to the disease reporting requirements relating to HIV. The amendments do not change the entities with a reporting responsibility under the current regulations. Healthcare practitioners currently report through keystroke entry into PA-NEDSS by clerical staff. All laboratories licensed by the Commonwealth to perform HIV and/or CD4 tests on specimens from Pennsylvania providers regardless of where the laboratory's testing facilities are located (*i.e.*, including laboratories licensed in Pennsylvania that may have testing facilities outside of the Commonwealth) are required to comply with the amendments as well.

The Department reviewed relevant Small Business Size Standards in 13 CFR Chapter 1, Section 121.201 (http://www.gpo.gov/fdsys/pkg/CFR-2011-title13-vol1/pdf/CFR-2011-title13-vol1-sec121-201.pdf), specifically Sector 62 – Health Care and Social Assistance. The Department identified categories of health care providers and clinics that are likely to diagnose diseases required to be reported. Additionally, the Department obtained small business information from the Department of Labor and Industry. Based on those data, the Department determined an estimate of the number of businesses in the Offices of Physicians category (621111), and Medical Laboratories (621511) that qualify as small businesses (<50 employees).

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

The financial and economic impact of the amendments outside of healthcare settings would be very minimal. Healthcare practitioners and clinical laboratories have been required to have systems in place to report some CD4 and HIV viral load test results into the Department's electronic disease surveillance system since 2006, so although the amendments will result in reporting of all CD4 and HIV viral load results and genotyping test results, these reporters do not need to develop new systems. Prior to these amendments healthcare practitioners and clinical laboratories would have had to separate CD4 and viral load test results based on regulation, reporting some, and not reporting others. This process takes time and adds cost. The amendments allow reporting of all test results, removing the need to separate the results into those reported and those not reported before sending them to the Department. Healthcare practitioners and laboratories without the ability to send data electronically directly to the Department's electronic disease surveillance system will be required to keystroke enter these additional test results

into that system. However, most CD4 and HIV viral load information is received from clinical laboratories with IT systems allowing direct electronic access. For these facilities, once their IT system is modified to capture the additional test results, the data would be automatically extracted and uploaded to the Department, so there would be no ongoing cost associated with the amended reporting requirements.

Moreover, the ongoing savings each year from more effective HIV disease control, prevention, and timely treatment of individuals infected with HIV is immeasurable. All Pennsylvanians would benefit from these amendments through the improved tracking of trends in HIV infection and treatment success, as well as assisting patients with linkage to care and treatment before they develop significant and expensive medical complications. These amendments help to protect Commonwealth citizens from exposure to HIV and subsequent hardship, disability, or death. In addition, the amendments enable the Commonwealth to comply with CDC recommendations for effective HIV disease surveillance, control and patient management, and enable the Department to protect persons living in the Commonwealth in the same way as 56 other states are able to do. With the implementation of these regulations, Pennsylvania will join all but 3 other states and territories in the requiring of the reporting of all CD4 T-lymphocytes and will leave Idaho as the lone state not requiring the reporting of all viral load results.

From a societal perspective, the spread of HIV, a virus that can lead to Acquired Immunodeficiency Syndrome (AIDS) if left untreated, is a serious public health issue. By the end of 2018, 36,136 individuals were diagnosed and living with HIV infection in this Commonwealth. 5,565 new HIV cases were diagnosed in the last five years (2014 to the end of 2018), accounting for 15.4% of all of those diagnosed and living with HIV infection by 2018. The estimated number of persons living with HIV has increased each year on average by approximately 1,200 persons. With a growth curve following a very strong linear trend, projections indicate that by 2025, there could be as many as 45,000 individuals in this Commonwealth living with HIV infection.

In order to stop the spread of HIV, prevent the emergence of new cases, and keep those persons living with HIV healthy, it is necessary to know where and how HIV is spreading. Those tested for HIV have a recorded CD4 count and viral load, which test results are indicators of HIV progression within the body. Currently, the Department does not require the reporting of all CD4 and viral load test results. This makes the current information reported incomplete, severely limiting the Department's ability to comply with current CDC standards, accurately report on CDC required core HIV indicators, and monitor and enhance patient outcomes across the continuum of HIV care services. Without this rulemaking, the reporting within the Commonwealth incomplete. Not having these reporting requirements in place has severely limited the Department's ability to comply with standards set by the CDC recommendations, accurately report on CDC-required core HIV indicators, and monitor and enhance patient outcomes across the continuum of HIV care services.

Ultimately, requiring the reporting of all CD4 T-lymphocyte and viral load test results will allow the Department to better track the epidemic in the Commonwealth, focus resources to meet the needs of the communities impacted, and improve the health of the citizens of the Commonwealth. *See National HIV/AIDS Strategy*, at 46. In addition, the Department is better able to ensure that those identified to be infected/living with HIV have access to care, are engaged in care and are virally suppressed. *See, e.g., National HIV/AIDS Strategy*; *see also* Exhibit D at p. 96 ("Data collected through the national HIV surveillance system can be used to monitor the outcomes of the national strategy; however the validity of these measures is dependent upon the completeness and quality of the surveillance data.")

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

The economic costs of these amendments are minimal. The costs associated with additional reporting of CD4 and HIV viral load tests and reporting of genotyping tests is outweighed by the financial, societal, and health benefits of tracking trends in HIV infection more completely and assisting patients with prompt linkage to care and treatment.

In addition, Pennsylvania currently is one of only 4 states in the nation that do not require the reporting of all CD4 test results. *See Exhibit "C"; see also* http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-21-4.pdf, at p. 63. Accessed February 23, 2018. In addition, of the 50 states, only Pennsylvania and Idaho fail to require the reporting of all viral load test results. *See Exhibit "C."* Goal 1 of the National HIV/AIDS Strategy, which calls for reducing new HIV infections, *see National HIV/AIDS Strategy* at 1, sets forth as a recommended action the allocation of public funding consistent with the geographic distribution of the epidemic. *Id.* at 19. The Strategy recommends a similar action with regard to Goal 4, achieving a more coordinated national response to the HIV epidemic. *Id.* at 43; *see also* 45 ("The Federal government should review the methods used to distribute Federal HIV funds and take steps to ensure that resources go to the States and localities with the greatest burden of disease.") If, in the future, federal funding is tied to disease burden, the Commonwealth would be at a disadvantage among other states with more complete data. The letter sent to Dr. Murphy in 2017 notes that other states, with complete reporting, are better able to monitor their success, have increased reporting, have more accurate and more timely HIV surveillance data, and are using the data to inform public health action. *See* Exhibit "B." Failure to update the Department's regulations will place the Commonwealth at a disadvantage against these other states.

Ultimately, requiring the reporting of all CD4 T-lymphocyte and viral load test results will allow the Department to better track the epidemic in the Commonwealth, focus resources to meet the needs of the communities impacted, and improve the health of the citizens of the Commonwealth. *See National HIV/AIDS Strategy*, at 46. In addition, the Department is better able to ensure that those identified to be infected/living with HIV have access to care, are engaged in care and are virally suppressed. *See, e.g., National HIV/AIDS Strategy*; *see also* Exhibit D at p. 96 ("Data collected through the national HIV surveillance system can be used to monitor the outcomes of the national strategy; however the validity of these measures is dependent upon the completeness and quality of the surveillance data.")

In addition, the Department notes that there is a risk of losing federal dollars if federal funding were to be targeted at states that can demonstrate the greatest burden of disease, and the Commonwealth were to lack the requirement for complete reporting that is created by this rulemaking. At the present time, the Commonwealth is one of only 4 states that fail to require the reporting of all CD4 results, and one of only two that does not require the reporting of all viral load results. This puts the Commonwealth at a severe economic disadvantage should the federal government choose to base funding on disease burden. Such an action is not beyond the realm of possibility; it would be in line with changes made to the CARE Act at the time the Department made HIV reportable by name in the Commonwealth in 2002, almost the last state in the country to take that action. At that time, the federal agency that provides funding for HIV/AIDS services, the Health Services Resource Administration (HRSA), changed its rules to condition the apportionment of state funding upon the number of live HIV cases within a jurisdiction, rather than live AIDS cases, based on changes to the CARE Act. *See The Ryan White CARE Act: A Side-by Side Comparison of Prior Law to the Newly Reauthorized CARE Act*, The Henry J. KAISER FAMILY Foundation, December 2006, at 3 (https://www.kff.org/wp-content/uploads/2013/01/7531-03.pdf), accessed October 28, 2019. Although the enforcement of this formula was delayed some years, HRSA eventually required all states to institute name-based HIV

reporting in order to meet the level of accuracy for the data demanded to support a fiscal claim by the state. *Id.*, *see also* HIV Prevalence Estimates – United States, 2006, MMWR 57(39);1073-1076 October 3, 2008), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a2.htm , accessed October 28, 2019. A similar circumstance could arise here, and states with more reliable data could receive the bulk, potentially all, of available federal funding, leaving the Commonwealth among only three or four states with no ability to reliably provide data.

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

The impact of the proposed amendments should be minimal. Healthcare practitioners and clinical laboratories currently are required to have systems in place to report some CD4 and HIV viral load test results into PA-NEDSS, so although the proposed amendments would result in reporting of all CD4 and HIV viral load results and genotyping test results, these reporters would not need to develop new systems. Currently, healthcare practitioners and clinical laboratories have to separate CD4 and viral load test results to eliminate those that are not reportable under the current regulations, and this process takes time and adds cost. The proposed amendment would require them to report all the test results and remove the need to separate the results before reporting; thereby saving them time from separating the test results. Healthcare practitioners and laboratories without the ability to send data electronically directly to the Department would be required to keystroke enter these additional test results into PA-NEDSS. However, most CD4 and HIV viral load information is received from clinical laboratories with IT systems allowing direct electronic access and data upload. For these facilities, once their IT system is modified to capture the additional test results, the data would be automatically extracted and uploaded to the Department's electronic disease surveillance system, so there would be no ongoing cost associated with the additional reporting requirements. Therefore, the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

In considering the issue of manual reporting, the Department reviewed data relating to reporting of CD4 and viral load test results from 2016-2019. Of the 175,965 HIV-related reports submitted by hospitals and laboratories to the Department, only 9,277, or roughly 5%, were reported manually. The data show that hospitals and laboratories that report a relatively small volume of cases are the entities that are reporting by manual entry. Hospital laboratories and commercial laboratories with larger volumes are more likely to report through batch reporting to the electronic laboratory reporting system. Once the parameters for sending data are updated, adding more reports to electronic feeds does not pose an ongoing burden to the laboratory. The Department is continuing to work with laboratories that are interesting in sending data through the electronic laboratory reporting system; however, some laboratories prefer manual reporting because they feel that the resources needed to report manually are less than those needed to establish electronic batch reporting.

The Department is sensitive to cost concerns of its reporters, and there is a concern among some that requiring multiple reporters is a waste of effort and money. The Department, however, must view the resources, time, and costs needed for reporting in the context of the need to monitor and promote the health of the citizens of the Commonwealth. With respect to HIV, there is an urgent public health need to monitor the proportion of cases under care and the proportion of cases adequately treated. Adequate treatment improves the health of persons with HIV and reduces their need for more expensive medical interventions. Furthermore, at least four clinical trials published since 2016 have demonstrated that adequate treatment of cases (indicated by low or non-existent viral loads and normal CD4 counts)

dramatically reduces transmission of HIV. *See* Rodger A.J., Cambiano V., Bruun T., *et al.*, "Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy," *JAMA.* 2016;316(2):171–181, DOI:10.1001/jama.2016.5148 (July 12, 2016) (https://jamanetwork.com/journals/jama/fullarticle/2533066), accessed October 28, 2019; Cohen M.S., Chen Y.Q., McCauley M., *et al.*, "Antiretroviral Therapy for the Prevention of HIV-1 Transmission." NEW ENG. J. MED. 2016; 375:830-839. DOI:10.1056/NEJMoa1600693 (September 1, 2016) (https://www.nejm.org/doi/full/10.1056/NEJMoa1600693), accessed October 28, 2019; Bavinton B.R., Pinto A.N., Phanuphak N., *et al.*, "Viral Suppression and HIV Transmission in Serodiscordant Male Couples: an International, Prospective, Observational, Cohort Study," *The Lancet HIV 2018*; 5(8): e438-e447 (July 16, 2018) (https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(18)30132-2/fulltext), accessed October 28, 2018; Rodger A.J., Cambiano V., Bruun T., *et al.*, "Risk of HIV Transmission through Condomless Sex in Serodifferent Gay Couples with the HIV-Positive Partner Taking Suppressive Antiretroviral Therapy (PARTNER): Final Results of a Multicentre, Prospective, Observational Study," *The Lancet 2019*; 393(10189): P2428-2438 (June 15, 2019) (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30418-0/fulltext), accessed October 28, 2019.

As the Department has said in the past when confronted with the same issue:

> With respect to issues involving the requirement of multiple reporters, the Department requires reporting from all different types of reporters, including practitioners, facilities, laboratories, other providers and the public for several reasons. The Department does not want possible reporters to self-censor, based on their assumption that another person will make the report. That could lead to under-reporting, and jeopardize the ability of the public health system to positively impact the health of infected individuals and their contacts. If the Department and local health departments are unaware of cases, they will be unable to offer or provide follow-up, including counseling and referral information, and perform case investigation.
>
> The Department also receives different information from different reporters. For example, a report by a laboratory is a confirmatory report of a disease or condition diagnosed by a health care practitioner. From heads of institutions the Department will receive information that is neither a diagnosis nor a confirmed report, but a suspicion that may help to identify a disease outbreak. The monitoring of the disease in the patient is dependent on receiving information from a practitioner as well as a laboratory, as is the monitoring of the disease in the population as a whole. Information relating to opportunistic infections, referrals, mode of transmission and treatment are not shared by a practitioner with the laboratory, and, therefore, the Department would not be able to obtain this type of specific information from laboratories if laboratories alone were to report. A provider would not release this type of information to a laboratory because of its confidential nature. A laboratory does not need to be aware of the mode of transmission of a disease or types of referrals made for the individual to perform its licensed function--conducting laboratory tests of specimens.
>
> The more specific the information received by the Department from all reporters, the more likely it is that the Department will be able to match information obtained from other sources, sometimes incomplete, and obtain complete information on each reported case. The more complete the demographic picture of the individual whose results are being reported, the easier it is for the Department to track the disease in this Commonwealth for purposes of implementing prevention measures, including targeting funding to affected populations. Further, the more

complete the information on a specific individual the Department obtains, the easier it becomes for the Department and local health departments to provide follow-up services to that individual. For example, with a case of infectious tuberculosis, the Department will provide treatment, including directly observed therapy, to ensure that the case is cured, and will also locate and test and treat contacts as necessary. In the case of sexually transmitted diseases, the Department and local departments locate and offer counseling and testing services to partners of individuals who test positive.

See Reporting of Communicable and Noncommunicable Diseases, 32 Pa.B. 491, 492-493 (January 26, 2002) https://www.pabulletin.com/secure/data/vol32/32-4/32-4.pdf, accessed October 28, 2019; *see also Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV*, 32 Pa. B. 3597, 3602 (July 20, 2002) https://www.pabulletin.com/secure/data/vol32/32-4/161.html, accessed October 28, 2019.

Identifying populations or areas with substandard levels of treatment could lead to interventions, such as improving linkage to care in underserved populations, that could eventually significantly reduce the Commonwealth's burden of HIV. In 2010 dollars, the lifetime treatment cost of one HIV case is approximately $379,668.00. https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html. Prevention of new cases, by, among other things, continuing existing cases in treatment and suppressing viral load is an obvious cost savings to the Commonwealth. The cost savings of a case of HIV averted has been estimated at between $ 20,000 to $100,000 per case. *See* Woodak and Cooney, "Do Needle Syringe Program Reduce HIV Infection Among Injecting Drug Users: A Comprehensive Review of the International Evidence," *Substance Use & Misuse*, Vol. 41, 2006 (Issue 6-7) at 20-22; *see also* "Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users," *(Evidence for Action Technical Papers) World Health Organization (2004) ("WHO White Paper")*, at 15-16. The Commonwealth saw 991 new cases of HIV in 2016. Pennsylvania Department of Health, *Annual HIV Surveillance Summary* (2016) http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/E-H/HIV%20And%20AIDS%20Epidemiology/Documents/Pennsylvania%202016%20Annual%20HIV%20Surveillance%20Report.pdf, accessed July 2, 2018. Using these figures, the cost to the Commonwealth of those 991 cases could be as high as $376,250,998.00. Preventing them from occurring could be a savings of as much as $99,100,000. Although determining the actual cost that the amendments will impose on providers and laboratories is not possible, it is extremely unlikely that this cost would outweigh the benefits of eventually improving the health of persons infected with HIV and decreasing the number of new cases of HIV.

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

The costs to both state and local governments will not increase as a result of these amendments. Costs to those entities already exist, since the Department and state and local health departments currently are required to track, through electronic reporting, over 50 reportable diseases and conditions, and undertake prevention and intervention activities when necessary. HIV, including CD4 counts, has been reportable by case name since 2002. The methodologies, including any legal, accounting or consulting procedures for reporting those cases have been in place since then and are already being utilized by those local health departments. Those local health departments (and the Department) are also already carrying out

prevention and intervention strategies to help prevent the spread of those diseases and get persons into treatment and keep them in treatment. Requiring the reporting of all CD4 counts, viral loads and genotyping will not create more processes, but will enable the Department and local health departments to utilize existing methods and processes in a more targeted way and more efficiently. The information will enable the Department and local health departments to focus on areas where funding and time need to be spent, and on persons who for one reason or another are unable to remain in treatment.

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

The costs to both state and local governments would not increase as a result of these regulations. Costs to those entities already exist, since DOH and state and local health departments currently are required to track, through electronic reporting, over 50 reportable diseases and conditions, and undertake prevention and intervention activities when necessary. HIV, including CD4 counts, has been reportable by case name since 2002. The methodologies, including any legal, accounting or consulting procedures for reporting those cases have been in place since then and are already being utilized by those local health departments. Those local health departments (and the Department) are also already carrying out prevention and intervention strategies to help prevent the spread of those diseases and get persons into treatment and keep them in treatment. Requiring the reporting of all CD4 counts, viral loads and genotyping will not create more processes, but will enable the Department and local health departments to utilize existing methods and processes in a more targeted way and more efficiently. The information will enable the Department and local health departments to focus on areas where funding and time need to be spent, and on persons who for one reason or another are unable to remain in treatment.

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

Healthcare practitioners and clinical laboratories have been required to have systems in place to report some CD4 and HIV viral load test results into the Department's electronic disease surveillance system since 2006, so although the amendments will result in reporting of all CD4 and HIV viral load results and genotyping test results, these reporters do not need to develop new systems. Prior to these amendments healthcare practitioners and clinical laboratories would have had to separate CD4 and viral load test results based on regulation, reporting some, and not reporting others. This process takes time and adds cost. The amendments allow reporting of all test results, removing the need to separate the results into those reported and those not reported before sending them to the Department. Healthcare practitioners and laboratories without the ability to send data electronically directly to the Department's electronic disease surveillance system will be required to keystroke enter these additional test results into that system. However, most CD4 and HIV viral load information is received from clinical laboratories with IT systems allowing direct electronic access. For these facilities, once their IT system is modified to capture the additional test results, the data would be automatically extracted and uploaded to the Department, so there would be no ongoing cost associated with the amended reporting requirements.

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

No. No new forms are required for reporting under these amendments. The amendments require reporting through an existing electronic disease surveillance system that has been in place in the

Commonwealth since 2002. The Department's general disease regulations at that time did make reference to paper reporting, and to a reporting system that existed prior to the implementation of electronic reporting. The Department first required electronic reporting of reportable diseases, infections, and conditions in a rulemaking published in the *Pennsylvania Bulletin* on January 26, 2002. *See Reporting of Communicable and Noncommunicable Diseases, supra.* In order to provide enough time for reporters other than laboratories to prepare for electronic reporting, (laboratories were required to report electronically immediately upon that rulemaking's publication), the Department set the implementation date of the electronic reporting requirement for most diseases, infections and conditions for six months after notice was published in the *Pennsylvania Bulletin*. Because that language is no longer applicable in 2019, and electronic reporting has long been in place in the Commonwealth, the Department deleted this language in amending Section 27.4(b). See 28 Pa. Code § 27.4(b).

By 2006, the Department had required that reports of all reportable diseases, infections and conditions were to be made electronically. *See Electronic Reporting Requirements for Specified Diseases, infections and Conditions*, 35 Pa.B. 6192 (Nov. 4, 2005). That requirement remains in place. Paper reporting is slow and inefficient and requires resources for processing and key entry that the Department does not have. Section 27.4 is amended in this final rulemaking to emphasize the Department's position.

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

Required reporters such as clinical laboratories, hospitals and practitioners currently report to the Department electronically through its electronic disease surveillance system, PA-NEDSS. https://www.nedss.state.pa.us/nedss/ No new forms are required for reporting under these amendments. The amendments require reporting through an existing electronic disease surveillance system that has been in place in the Commonwealth since 2002. The Department's general disease regulations at that time did make reference to paper reporting, and to a reporting system that existed prior to the implementation of electronic reporting. The Department first required electronic reporting of reportable diseases, infections, and conditions in a rulemaking published in the *Pennsylvania Bulletin* on January 26, 2002. *See Reporting of Communicable and Noncommunicable Diseases, supra.* In order to provide enough time for reporters other than laboratories to prepare for electronic reporting, (laboratories were required to report electronically immediately upon that rulemaking's publication), the Department set the implementation date of the electronic reporting requirement for most diseases, infections and conditions for six months after notice was published in the *Pennsylvania Bulletin*. Because that language is no longer applicable in 2019, and electronic reporting has long been in place in the Commonwealth, the Department deleted this language in amending Section 27.4(b). See 28 Pa. Code § 27.4(b).

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

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community[1]	0.00	0.00	0.00	0.00	0.00	0.00
Local Government[2]	0.00	0.00	0.00	0.00	0.00	0.00
State Government[3]	0.00	0.00	0.00	0.00	0.00	0.00
Total Savings						
COSTS:						
Regulated Community[4]	0.00	0.00	0.00	0.00	0.00	0.00

[1] Because the amendments require the reporting of all test results, the regulated community would no longer be required to use staff time to separate out those results that are reportable from those that are not. Although this should result in some cost savings to reporters, the amount is in all probability too small to quantify.

[2] DOH and local government, to the extent local government is the county and municipal health departments who also have the same responsibility for disease prevention and control in their jurisdiction as does DOH, will have minimal costs. DOH and the county/municipal health departments already have an electronic reporting system in place (PA-NEDSS) that is being utilized to report some of these results now. In addition, while DOH and the county and municipal health departments may have more reports to review, the more cases that are reported and entered into and maintained in care, the less overall cost there is to the Commonwealth, local governments and society in terms of medical treatment, social services, and other care. If a client's viral load remains suppressed, the transmission of HIV becomes extremely unlikely. Reporting all viral loads and CD4 counts provide practitioners and public health officials with important information enabling them to ensure clients are obtaining necessary treatment and remain there. In 2010, the cost per one HIV case in the Commonwealth over a life time was approximately $379,668. https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html. Prevention of new cases, by, among other things, continuing existing cases in treatment and suppressing viral load is an obvious cost savings to the Commonwealth.

[3] See Footnote 2, supra.

[4] Because some reporters feel that they do not report enough to report electronically, the increase in the number of reports required may make the reporter decide to upgrade its reporting system. These would be costs that are voluntary on the part of the reporter, however. DOH does provide for manual reporting, by allowing reporters to enter keystrokes manually into PA-NEDSS rather than having a reporter's electronic medical record. This could create additional staff time and may result in additional costs as well. The number of manual reporters are minimal, and the cost to that regulated community should also be minimal. In considering the issue of manual reporting, the Department reviewed data relating to reporting of CD4 and viral load test results from 2016-2019. Of the 175,965 HIV-related reports submitted by hospitals and laboratories to the Department, only 9,277, or roughly 5%, were reported manually. The data show that hospitals and laboratories that report a relatively small volume of cases are the entities that are reporting by manual entry. Hospital laboratories and commercial laboratories with larger volumes are more likely to report through batch reporting to the electronic laboratory reporting system. Once the parameters for sending data are

Local Government[5]	0.00	0.00	0.00	0.00	0.00	0.00
State Government[6]	0.00	0.00	0.00	0.00	0.00	0.00
Total Costs	0.00	0.00	0.00	0.00	0.00	0.00
REVENUE LOSSES:						
Regulated Community	0.00	0.00	0.00	0.00	0.00	0.00
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00
Total Revenue Losses	0.00	0.00	0.00	0.00	0.00	0.00

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

Program	FY -3	FY -2	FY -1	Current FY
AIDS and Special Pharmaceutical Services	$17,436,000	$17,436,000	$12,436,000	$12,436,000

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

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(a) Please see the responses to questions 15, 16, 17 and 19. There should be no adverse impact to small business, since these amendments simply extend the numbers of cases being reported, the systems through which reporting is to occur are already in place and being utilized.

updated, adding more reports to electronic feeds does not pose an ongoing burden to the laboratory. The Department is continuing to work with laboratories that are interesting in sending data through the electronic laboratory reporting system; however, some laboratories prefer manual reporting because they feel that the resources needed to report manually are less than those needed to establish electronic batch reporting.

[5] See Footnote 2, supra.

[6] See Footnote 2, supra.

(b) Please see the responses to questions 15, 16, 17 and 19. There should be no adverse impact to small business, since these amendments simply extend the numbers of cases being reported, the systems through which reporting is to occur are already in place and being utilized.

(c) Because some clinical laboratories, hospitals and practitioners would be considered to be small businesses, the impact on those entities would be as outlined in the responses to questions 15, 16, 17 and 19. Hospitals, practitioners and laboratories are currently required to report recognized communicable diseases and that requirement would continue under these proposed amendments. Any increase in reporting responsibilities as a result of these proposed changes to disease reporting regulations would be minimal as the reporting systems are already in place and HIV test reporting is already occurring. Moreover, these reports could be made electronically or by telephone call to a local health department as needed. There are no special requirements other than clerical skills. There are no alternatives that are less intrusive or costly to the current approaches for disease reporting in proposed amendment that would allow the Department and local health departments to receive timely reports of communicable diseases that may pose public health threats.

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

Because the purpose of these amendments is the prevention and control of the spread of disease, there are no special provisions that have been developed to meet the particular needs of affected groups or persons. Compliance from all regulated communities is necessary to effectively combat the spread of disease and to implement effective education and prevention programs within the Commonwealth.

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

The purpose of these amendments is the prevention and control of the spread of disease. Compliance, including reporting, from all regulated communities, with these amendments is necessary to effectively combat the spread of disease and to implement effective education and prevention programs within the Commonwealth. Therefore, there were no alternative regulatory provisions considered. All health care practitioners, health care facilities, and clinical laboratories are currently required by law to report recognized communicable diseases (*see* 35 P.S. § 521.4) and that requirement would continue under these amendments. Any increase in reporting responsibilities as a result of amendments to the disease reporting regulations would be minimal as the reporting systems are already in place and reporting of HIV testing and some CD4 T-lymphocyte test results is already occurring. There are no alternatives that are less intrusive or costly to the current approaches for disease reporting that would allow the Department to receive timely reports of communicable diseases that may pose public health threats. Therefore, the Department is pursuing the least burdensome acceptable alternative.

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

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

(a) To the extent health care practitioners, clinical laboratories, or entities providing HIV services are considered small businesses, there are no provisions in the amendments to the communicable disease regulations that would impose an added burden to the small business community beyond that which already existed based on the Department's regulations. The Department is expanding existing reporting categories to require all reporting, rather than some reporting.

The small businesses that have been and would continue to be impacted by these regulations are healthcare providers that identify and report HIV/AIDS and laboratories that test specimens submitted by healthcare practitioners that identify the presence of HIV/AIDS. There are no small businesses that can be exempted from the disease control requirements of the amendments, since the Department's purpose is to prevent and control the spread of disease throughout the Commonwealth and needs information from all possible reporting sources.

(b) Because of the importance of timely reporting in order to obtain accurate information, therefore enabling the Department and local health departments to institute timely and effective public health interventions and getting infected persons into treatment more quickly, the Department did not amend existing time frames for reporting CD4 T-lymphocyte test results and other HIV test results. Before these amendments were proposed, the regulations required reporting of these results within 5 days of receipt of the test result; the amendments, while requiring reporting of all tests, do not change the time frames for reporting. Five days is the longest time period in the Department's reporting regulations.

(c) In requiring disease reporting, the Department's goal is to obtain reports of all existing disease cases. In order to obtain the highest number of reports possible, and the most complete reporting possible, the Department requires reporting from a number of sources. *See Reporting of Communicable and Noncommunicable Diseases*, 32 Pa.B. 491, 492-493 (January 26, 2002) https://www.pabulletin.com/secure/data/vol32/32-4/32-4.pdf, accessed October 28, 2019; *see also Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV*, 32 Pa. B. 3597, 3602 (July 20, 2002) https://www.pabulletin.com/secure/data/vol32/32-4/161.html, accessed October 28, 2019. For this reason, the Department has not consolidated reporting requirements. The amendments, however, simplify reporting, since required reporters are no longer be required to separate out those results that do not meet the current levels set for reporting CD4 T-lymphocyte test results and viral loads.

(d) The Department has not altered the requirements of its reporting regulations, except to expand the number of tests being reported. The manner in which the reporting would occur, that is, through the Department's electronic disease surveillance system, does not change, nor does the time frame in which the reporting must occur.

(e) There are no small businesses that can be exempted from the disease control requirements of the amendments, since the Department's purpose is to prevent and control the spread of disease throughout the Commonwealth and needs information from all possible reporting sources.

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

The Department has relied upon recommendations by the CDC and on the *National HIV/AIDS Strategy, updated for 2020*. In order to achieve the goals set out in the *National HIV/AIDS Strategy for the United States, updated for 2020* (July 2015), at Executive Summary 3, https://files.hiv.gov/s3fs-public/nhas-update.pdf. Accessed February 23, 2018 (hereinafter referred to as "*National HIV/AIDS Strategy*"), the CDC recommends, among other things, the reporting of all HIV-results (counts and percentages) and all viral load results (undetectable and specific values). *See Letter from Kenneth G. Castro, M.D., Assistant U.S. Surgeon General, U.S. Public Health Service and Amy Lansky, Ph.D., M.P.H., Deputy Director for Surveillance, Epidemiology and Laboratory Sciences, Division of HIV Prevention, CDC*, a copy of which is attached hereto as Exhibit "A". A letter directly to the former Secretary of Health, Karen Murphy, from the Director of the Office for State, Tribal, Local and Territorial Support and Deputy Director of the CDC, reiterated this position to the Commonwealth, as one of four states that do not collect CD4 test results. *See* Exhibit "B". In addition, of the 50 states, only Pennsylvania and Idaho fail to require the reporting of all viral load test results. *See* Exhibit "C."

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

A. The length of the public comment period:	30 days
B. The date or dates on which any public meetings or hearings will be held:	See below.
C. The expected date of delivery of the final-form regulation:	See below.
D. The expected effective date of the final-form regulation:	See below.
E. The expected date by which compliance with the final-form	

regulation will be required:	See below.
F. The expected date by which required permits, licenses or other approvals must be obtained:	N/A

A. The agency accepted public comment for 30 days after publication of the proposed rulemaking in the *Pennsylvania Bulletin* on May 25, 2019. *See* 49 Pa.B. 2605 (May 25, 2019).

B. The Department held a meeting of the Advisory Health Board to review and approve the proposed regulations on two occasions: July 25, 2018 and September 18, 2018. Both meetings were public meetings at which the Department presented the proposed regulations to the Board for its review and approval. The Department published notice of the July meeting in the *Pennsylvania Bulletin* on July 21, 2018 (48 Pa.B. 4354 (July 21, 2018)), and of the September meeting on September 15, 2018 (48 Pa.B. 5805 (September 15, 2018)), in advance of the meetings, and in accordance with the requirements of the Sunshine Law. The Board voted on September 18, 2018 to approve the proposed regulations. The Advisory Health Board met again on January 14, 2020, to review the Final Rulemaking, and discussed and approved the Final Rulemaking on that date. Advanced notice of that meeting was published in the *Pennsylvania Bulletin* on December 21, 2019. (49 Pa.B. 7505 (December 21, 2019)).

C. The Department expects to publish Final Rulemaking in the *Pennsylvania Bulletin* on or before July of 2020.

D. The Department expects that the Final Rulemaking will be effective on the date of publication in the *Pennsylvania Bulletin.*

E. Compliance would be required on the date of publication in the *Pennsylvania Bulletin.*

F. Permits, licenses or other approvals would not be required by this Rulemaking.

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

The Department continually reviews the validity and efficacy of its regulations.

EXHIBIT "A"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention

November 21, 2013

Dear Colleague:

Measuring progress towards goals of the National HIV/AIDS Strategy (NHAS) relies on laboratory reporting of HIV-related tests to the local and national HIV surveillance systems. The Centers for Disease Control and Prevention (CDC) recommends reporting of all HIV-related test results, including CD4+ T-lymphocyte (CD4) results and all viral load test results. This comprehensive laboratory reporting recommendation is in alignment with the Council of State and Territorial Epidemiologists' (CSTE) position (ID: 2001-ID-03 Committee: Infectious Disease Title: The impact of new technologies and therapies on HIV/AIDS surveillance: routine nationwide reporting of CD4, STAHRS, antiretroviral resistance, and viral load test results).

Laboratory data, including CD4 and viral load test results, are an essential component of the national HIV surveillance system. CD4 and viral load data can be used to identify cases, classify stage of disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into care and retention in care, measure viral load suppression, and assess unmet health care needs. Analyses at the national level to monitor progress against HIV can only occur if all HIV-related CD4 and viral load test results are reported by all jurisdictions.

States with laws, regulations, or policies that support the reporting of all CD4 and viral load test results to HIV surveillance programs have increased reporting and improved completeness and timeliness of HIV surveillance data. Although all states have reporting laws, regulations, or policies, the level at which results must be reported varies. A state, for example, may require only data for CD4 counts above 500 or detectable viral load results be reported. CDC recommends the reporting of all HIV-related CD4 results (counts and percentages) and all viral load results (undetectable and specific values). Where laws, regulations, or policies are not aligned with these recommendations, states might consider strategies to best implement these recommendations within current parameters or consider steps to resolve conflicts with these recommendations. In addition, reporting of HIV-1 nucleotide sequences from genotypic resistance testing might also be considered to monitor prevalence of antiretroviral drug resistance, and HIV genetic diversity subtypes and transmission patterns.

Consistent with the terms of CDC's HIV surveillance cooperative agreement with state and local health departments, CDC requires entry of all HIV-related laboratory test results for persons diagnosed with HIV into the state or local eHARS database for submission to CDC for inclusion in national analyses. To achieve maximal efficiency and accuracy of reporting, laboratories, health care providers, and other facilities are encouraged to report HIV-related laboratory test results electronically to the state/local health department when possible. Laboratories are encouraged to follow the HL7 Version 2.5.1 Implementation Guide: Electronic Lab Reporting to Public Health, Release 1 (US Realm) with Errata. HIV reports should be encrypted using

methods that meet Federal Information Processing Standards (FIPS) Publication 197, ADVANCED ENCRYPTION STANDARD (AES) (See http://csrc.nist.gov/publications/fips/fips197/fips-197.pdf.) and sent securely to the state/local health department along with results from all other reportable conditions. If reported to a central location within the health department, the data would then be parsed by the health department and HIV-related results shared with the HIV program.

The Epidemiology and Laboratory Capacity for Infectious Disease Cooperative Agreement (ELC) is a CDC cooperative agreement that includes support for implementing electronic laboratory reporting (ELR) solutions. The ELC has assisted many jurisdictions with developing an infrastructure for ELR. All jurisdictions receive ELC funds in some capacity, and most have taken advantage of these funds by implementing tools for receiving laboratory reports electronically. HIV programs are encouraged to leverage existing ELC-funded resources when implementing ELR.

Enhancements in electronic death reporting systems can also improve quality and timeliness of death ascertainment for persons with HIV and can be achieved through implementation of electronic death registration. Mortality surveillance is a core public health function and critical to HIV surveillance to ensure accurate estimates of prevalence and other related measures used to monitor the NHAS. HIV surveillance programs are encouraged to work with their Vital Records offices to support adoption of electronic death registration where possible.

CDC is committed to providing the technical assistance necessary to improve laboratory reporting so that it enhances, rather than disrupts, ongoing HIV surveillance. For further information, or to request technical assistance, you may contact Irene Hall, Ph.D., HIV Incidence and Case Surveillance Branch; Division of HIV/AIDS Prevention; National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; telephone (404) 639-2050 or e-mail (IHall@cdc.gov).

Thank you for your continued, dedicated efforts to prevent HIV infection in the United States.

Sincerely,

/Kenneth Castro/
RADM Kenneth G. Castro, M.D.
Assistant Surgeon General, U.S. Public Health Service
Commanding Flag Officer, CDC/ATSDR
Commissioned Corps

Acting Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

/Amy Lansky/
Amy Lansky, PhD, MPH
Deputy Director for Surveillance, Epidemiology, and Laboratory Sciences
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

References

Link to National HIV/AIDS Strategy:
http://www.whitehouse.gov/administration/eop/onap/nhas

Link to CSTE position statement:
http://www.cste.org/ps/pssearch/2001final/2001-ID-03.pdf#search="hiv

EXHIBIT "B"

From: OSTLTS Director (CDC) [mailto:OSTLTSDirector@cdc.gov]
Sent: Wednesday, February 08, 2017 2:39 PM
To: Murphy, Karen <karmurphy@pa.gov>
Cc: Mermin, Jonathan (CDC/OID/NCHHSTP) <jhm7@cdc.gov>; McCray, Eugene (CDC/OID/NCHHSTP) <ecm1@cdc.gov>
Subject: Reporting of HIV-Related Test Results

Dear Dr. Murphy:

The Centers for Disease Control and Prevention (CDC) recommends that states require reporting of all HIV-related test results; however there is more work to do to achieve this goal in all states. CDC recognizes the progress states have made to modify reporting regulations to include all HIV-related test results and is committed to providing the technical assistance necessary to improve laboratory reporting in states so that it enhances, rather than disrupts, ongoing HIV surveillance. This letter provides information about the importance of required reporting and how to request technical assistance from CDC related to that issue.

The updated National HIV/AIDS Strategy for the United States identifies primary goals to guide our collective national fight against HIV. The success in advancing several of these goals, ensuring sustained viral suppression for persons living with HIV and measuring progress towards HIV care, relies on laboratory reporting of HIV-related tests, including all CD4+ T-lymphocyte (CD4) and viral load test results, to local and national HIV surveillance systems. Complete laboratory data are critical to identifying cases, measuring care and treatment outcomes, and measuring the effectiveness of public health interventions. Specifically, these data are often used to monitor disease progression, determine the stage of HIV infection, monitor receipt of HIV care and treatment, and make decisions about public health interventions. Both viral load and CD4 data are used to assess whether patients are responding to treatment: when treatment is successful, CD4 counts rise and viral loads fall. Current HIV clinical management guidelines call for CD4 and viral load testing at the time of diagnosis and regularly thereafter. When all CD4 and viral load results are reported, public health agencies can determine access to care and treatment outcomes. For these reasons, CDC recommends complete state reporting of all HIV-related test results. Complete laboratory reporting is defined as

- The jurisdiction's laws/regulations require the reporting of all CD4 and viral load results to the state or local health department.
- Laboratories that perform HIV-related testing for the jurisdictions report minimum of 95% of HIV-related test results to the state or local health department.
- The jurisdiction reports (to CDC) at least 95% of all CD4 and viral load test results for the years being assessed.

To date, 32 states and the District of Columbia meet the criteria of complete laboratory reporting; 12 states, Puerto Rico, and the US Virgin Islands partially meet the criteria of complete laboratory reporting; and only six states have no laws or regulations for complete laboratory reporting.* States with laws, regulations, or policies that support the reporting of all CD4 and viral load test results to the state or local health department are better able to monitor their success, have increased reporting and improved completeness and timeliness of HIV surveillance data, and are using the data to inform public

health action. For example, many of these jurisdictions are using HIV surveillance data to identify HIV-diagnosed individuals who are not in care and link, engage, or re-engage them in HIV medical care. Jurisdictions also increasingly include laboratory reporting of HIV genetic information from routine testing for drug resistance as part of their reporting requirements as an indicator of care and to investigate potential transmission networks.

We understand that Pennsylvania requires reporting of CD4 counts below <200 cells/mm3 blood or <14% as well as reporting of viral loads (28 Pa. Code § 27.32a). We would encourage you to consider requiring reporting of all CD4 counts and both undetectable and detectable viral loads.

For additional information regarding CDC's recommendation to require state reporting of all HIV-related test results, or to request technical assistance, you may contact Dr. Angela Hernandez, HIV Incidence and Case Surveillance Branch, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention by telephone at (404) 639-8969 or by email at AHernandez@cdc.gov.

Thank you for your continued, dedicated efforts to prevent HIV infection in the United States.

Sincerely,

José T. Montero, MD, MHCDS
Director, Office for State, Tribal, Local and Territorial Support
Deputy Director, Centers for Disease Control and Prevention

And

Jonathan H. Mermin, MD, MPH
RADM and Assistant Surgeon General, USPHS
Director
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

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* http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-21-4.pdf (see last paragraph on page 5).

EXHIBIT "C"

Kostelac, Yvette

From: Selik, Richard (CDC/OID/NCHHSTP) <rms1@cdc.gov>
Sent: Wednesday, February 28, 2018 12:03 PM
To: Obiri, Godwin
Cc: Allen, Michael
Subject: RE: States Reporting All CD4 and VL Tests

Godwin,

Below is a summary of states that do not yet have complete VL and/or CD4 reporting laws.
As you can see:
only 6 US states (PA, Kansas, New Jersey, Vermont, and Idaho) do not mandate reporting of all CD4 test results, and only 2 US states (PA and Idaho) do not mandate reporting of all viral load test results.
You should probably not compare Pennsylvania with US territories.

US states	CD4 results that must be reported	VL results that must be reported
Kansas	<29%	Any result
New Jersey	<14%	Any result
Vermont	<14%	Any result
Idaho	<14%	Detectable
Pennsylvania	<14%	Detectable
US territories		
Virgin Islands, US	<14%	Detectable
American Samoa	None	None
Guam	None	None
Marshall Islands	None	None
Micronesia, FS	None	None
N. Mariana Islands	None	None
Palau	None	None

From: Obiri, Godwin [mailto:gobiri@pa.gov]
Sent: Wednesday, February 28, 2018 10:11 AM
To: Selik, Richard (CDC/OID/NCHHSTP)
Subject: States Reporting All CD4 and VL Tests

Richard,

My record shows that only 8 states are not currently reporting all CD4 test results while 6 states are not reporting all VL test results. Are these numbers correct at this point or have some states changed their HIV regulation in recent times?

Thanks,
Godwin Obiri, DrPH, MS. | Director, HIV Surveillance & Epidemiology
Bureau of Epidemiology
Pennsylvania Department of Health
625 Forster St. | Harrisburg, PA 17120
Phone: 717.783.0481 | Fax: 717.772.6975
Email: gobiri@pa.gov
www.Health.State.PA.US

Pennsylvania Department of Health HIV Surveillance & Epidemiology Reports

"Confidential Protected Health Information Enclosed"

Protected Health Care Information is personal and sensitive information related to a person's health care. You, the recipient, are obligated to maintain it in a safe, secure and confidential manner. Re-disclosure without additional patient consent or as permitted by law is prohibited. Unauthorized re-disclosure or failure to maintain confidentiality could subject you to penalties described in federal and state law.

Kostelac, Yvette

From: Selik, Richard (CDC/OID/NCHHSTP) <rms1@cdc.gov>
Sent: Tuesday, September 11, 2018 6:04 PM
To: Obiri, Godwin
Cc: Allen, Michael
Subject: States without complete cd4 & VL reporting

Godwin,

In May 2018, Kansas began to require reporting of all CD4 test results and all viral load results. That leaves only 4 states (Idaho, New Jersey, Pennsylvania, and Vermont) who do not yet do it.

Richard

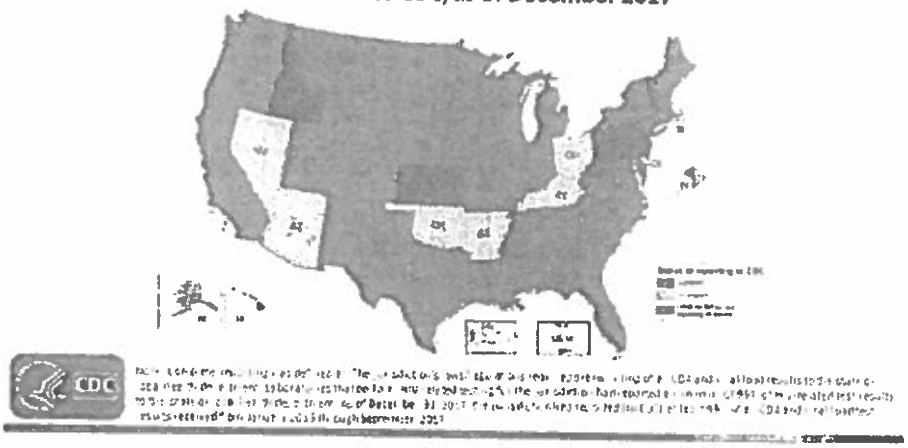
From: Peruski, Anne (CDC/OID/NCHHSTP)
Sent: Monday, July 9, 2018 10:56 AM
To: Satcher Johnson, Anna (CDC/OID/NCHHSTP) ; Selik, Richard (CDC/OID/NCHHSTP)
Subject: RE: states without complete cd4 reporting

In Arizona, a law requiring complete reporting became effective January 2018.

From: Satcher Johnson, Anna (CDC/OID/NCHHSTP)
Sent: Monday, July 9, 2018 10:55 AM
To: Selik, Richard (CDC/OID/NCHHSTP) <rms1@cdc.gov>; Peruski, Anne (CDC/OID/NCHHSTP) <xax7@cdc.gov>
Subject: RE: states without complete cd4 reporting

Hi Richard,
The states in red (Idaho, Kansas, New Jersey, Pennsylvania, Vermont, and USVI.

HIV Surveillance Reporting Areas with Complete Reporting of CD4 and Viral Load Test Results to CDC, as of December 2017



From: Selik, Richard (CDC/OID/NCHHSTP)
Sent: Monday, July 9, 2018 10:52 AM

To: Peruski, Anne (CDC/OID/NCHHSTP) <xax7@cdc.gov>; Satcher Johnson, Anna (CDC/OID/NCHHSTP) <ats5@cdc.gov>
Subject: FW: states without complete cd4 reporting

Anne or Anna,

Could you tell me which states besides Pennsylvania do not yet have complete CD4/Viral load reporting requirements?

Richard

From: Allen, Michael <michaealle@pa.gov>
Sent: Monday, July 9, 2018 10:45 AM
To: Selik, Richard (CDC/OID/NCHHSTP) <rms1@cdc.gov>
Subject: states without complete cd4 reporting

Richard,

Can you tell me which other states (I think it is 5 in total) do not yet have complete CD4/Viral load reporting requirements?

I believe we are making progress on this here in PA and we want to be able to tell the IRCC at an upcoming meeting in late July that only a handful of states are still lagging in addition to PA.

Thanks.

Michael Allen, MPH| Epidemiology Research Associate
Department of Health |Bureau of Epidemiology
625 Forster Street, Room 933 | Harrisburg, PA 17120
Phone: 717.547.3521 | Fax:717.772.6975
www.health.pa.gov

EXHIBIT "D"

HIV PLANNING GROUP

December 21, 2016

ATTN: GOVERNOR TOM WOLF

The HIV Planning Group (HPG) recommends mandating statewide reporting of all overdose cases treated in the medical system, as well as improving existing HIV surveillance by requiring viral load, CD4 count, and medication regimen information to be reported. We are also calling for additional State resources to be earmarked for these enhanced surveillance activities in order to support compliance and ensure data quality. The HPG is a group of diverse stakeholders united for the purpose of contributing to HIV care and prevention activity planning across the Commonwealth of Pennsylvania; the HPG assists the Pennsylvania Department of Health with the creation and execution of an Integrated HIV Care and Prevention Plan.

The Commonwealth is currently experiencing an epidemic of opioid use and unsafe injection practices, which has resulted in significant increases in rates of Hepatitis C (HCV) transmission and overdose fatalities. Due to common modes of HCV and HIV transmission, this indicates an increased risk of HIV incidence across the Commonwealth. Following the outbreak of over 200 new HIV cases in 10 months related to injection drug use in Scott County, Indiana, we strongly believe overdose reporting will help prevent an outbreak in the Pennsylvania.

Mandated reporting of CD4 and viral load aligns with the objectives of the National HIV/AIDS Strategy: focus on reducing new HIV infections, increase access to care, and improve outcomes for people living with HIV (PLWH). It would assist the Pennsylvania's Department of Health's ability to focus on having HIV-diagnosed individuals linked to care, retained in care, and virally suppressed. We believe the Commonwealth can optimally treat PLWH if we have accurate information about the continuum of care which comes with mandatory reporting.

This information drives our prevention and care efforts. It helps us with *data to care*, using data to make determinations about those who are in care, and identify individuals who are not in care in hopes of getting them linked back into care. We need this complete information in order to implement very specific activities to ensure viral suppression for everyone.

Data to care equals optimal results for the consumers we serve. We ask that you provide our planning body with a response to our request as earliest as you are able to and on behalf of the HPG we thank you for your consideration.

Richard Smith
Community Co-Chair

Christopher Garnett
Incidence Sub-Committee Chair

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your source for community HIV prevention and care

c/o HIV Prevention and Care Project
www.stophiv.com

EXHIBIT "E"

The Open AIDS Journal, 2012, *6*, (Suppl 1: M5) 90-97

Enhanced Collection of Laboratory Data in HIV Surveillance Among 5 States with Confidential Name-based HIV Infection Reporting, 2005-2006

Kristen Mahle Gray[*,1], Tebitha Kajese[2], Erin Crandell-Alden[3], Bridget J. Anderson[4], Debbie Wendell[5], Allison Crutchfield[6], Terry Jackson[7] and H. Irene Hall[1], for the Laboratory Reporting Workgroup[§]

[1]*Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA, USA*

[2]*Business Computer Applications, 2002 Summit Blvd, Suite 880, Atlanta, GA, USA*

[3]*HIV/STD/VH/TB Epidemiology Section, Division of Communicable Diseases, Bureau of Epidemiology, Michigan Department of Community Health, Lansing, MI, USA*

[4]*Bureau of HIV/AIDS Epidemiology, AIDS Institute, New York State Department of Health, Albany, NY, USA*

[5]*HIV/AIDS Program, Louisiana Office of Public Health, New Orleans, LA, USA*

[6]*Disease Control and Environmental Epidemiology Division, Colorado Department of Public Health and Environment, Denver, CO, USA*

[7]*Division of HIV/STD, Indiana State Department of Health, Indianapolis, IN, USA*

Abstract: Laboratory data reported through HIV surveillance can provide information about disease severity and linkage to care; however these measures are only as accurate as the quality and completeness of data reported. Using data from five states that implemented enhanced collection of laboratory data in HIV surveillance from 2005-2006, we determined completeness of reporting, stage of disease at diagnosis, the most common opportunistic illnesses (OI) at diagnosis, and linkage to medical care. Methods to enhance laboratory reporting included increasing active surveillance efforts, identifying laboratories not reporting to HIV surveillance, increasing electronic reporting, and using laboratory results from auxiliary databases. Of 3,065 persons ≥13 years of age diagnosed with HIV, 35.5% were diagnosed with stage 3 (AIDS) and 37.7% progressed to stage 3 within 12-months after diagnosis. Overall, 78.5% were linked to care within 3 months; however, a higher proportion of persons with ≥1 CD4 or viral load test was found among whites compared with blacks/African Americans (82.1% *vs* 73.6%, p<0.001). Few (12.3%) had an OI within 3 months of diagnosis. The completeness of laboratory data collected through surveillance was improved with enhanced reporting and provided a more accurate picture of stage of disease and gaps in linkage to care. Additional interventions are needed to meet the goals of the National HIV/AIDS Strategy on linkage to care and the reduction of HIV-related disparities.

Keywords: HIV diagnoses, HIV surveillance, CD4 and VL reporting, linkage to care.

INTRODUCTION

The clinical management of HIV disease relies on CD4+ T-lymphocyte (CD4) and plasma HIV-1 RNA (i.e., viral load) testing to guide the initiation of treatment and monitor care. The Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents recommend CD4 count and viral load (VL) testing for a new patient during the initial visit and every 3 to 4 months after HIV diagnosis. Among patients who are clinically stable, CD4 may be monitored less frequently (every 6-12 months) [1]. The reporting of CD4 and VL results to health departments enhances local and national HIV case surveillance data and is used to identify cases, stage disease at diagnosis, and monitor disease progression. CD4 and VL data can also be used to determine entry and retention in care, measure viral load suppression, and assess unmet healthcare needs; however these measures are only as accurate as the quality and completeness of data reported.

AIDS was a reportable condition by the mid-1980s in all 50 states and the District of Columbia; however AIDS surveillance was limited to the collection of clinical data. With the advent of antiretroviral medications, which have helped HIV-infected persons live longer, and the increased availability of HIV tests, the national focus has shifted to integrate AIDS surveillance and surveillance of HIV infection. In the early 1990s, surveillance programs began collecting CD4 test results as part of routine surveillance activities. This was in part a result of the expansion of the

*Address correspondence to this author at the HIV Incidence and Case Surveillance Branch, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention, Mailstop E-47, 1600 Clifton Road, NE, Atlanta, GA 30333, USA; Tel: 404-639-2050; Fax: 404-639-2980; E-mail: hlo9@cdc.gov

[§]Laboratory Reporting Workgroup Participants: Elizabeth Hamilton[5], Maria Kouznetsova[4] and Pamela Montoya[6]

1874-6136/12

AIDS case definition in 1993 to include an immunologic definition of AIDS; CD4 counts of less than 200 cells/mm^3 or CD4 percentages less than 14% of total lymphocytes [2]. For the first time, the AIDS case definition could be met based exclusively on a positive HIV test and a low CD4 count or percentage. The most recent revision of the HIV surveillance case definition, in 2008, highlights the central role of CD4 results by using CD4 counts and percentages to define three stages of HIV infection, increasing in severity from stage 1 through stage 3 (AIDS) [3]. An unknown stage was built into the case definition to account for cases that do not have CD4 results or information on AIDS-defining conditions. The 2008 case definition also incorporated a new role for viral load test results in surveillance, as a detectable viral load became sufficient criteria for establishing a case for surveillance purposes [3].

The majority of U.S. states have policies or regulations that require laboratories to report CD4 and VL results to health departments. However, the level at which these laboratory results are reported varies within and across jurisdictions. In addition, barriers to maintaining complete and timely laboratory data in surveillance systems exist and may include the management of a large volume of reports and the receipt of paper *vs* electronic reports.

We conducted enhanced data collection in five state HIV surveillance programs for CD4 and VL laboratory test results and OIs among newly diagnosed HIV-infected persons. Using these data, we evaluated the completeness of CD4 and VL laboratory reports collected through surveillance, determined stage of disease at diagnosis, the most common OIs reported at diagnosis, and linkage to medical care within 3 months of diagnosis using laboratory tests as a marker for receipt of care.

MATERIALS AND METHODS

Five surveillance jurisdictions (Colorado, Indiana, Louisiana, Michigan and New York [excluding New York City]) were selected to participate in the project as part of a competitive announcement. Analyses were based on data collected in the five states and reported to the Centers for Disease Control and Prevention (CDC) on HIV-infected persons aged 13 years or older diagnosed during April 2005 through March 2006, with the exception of New York, where persons were diagnosed from June 2005 through May 2006. Enhanced data collection of CD4 results, VL results, and OIs was conducted for all cases reported to the surveillance programs by 6 months after the end of the 12-month diagnosis period, except for Michigan where two out of three cases were sampled.

The five surveillance programs collected information according to routine surveillance procedures. Information was obtained on age, sex, race/ethnicity (white, black or African American, Hispanic or Latino, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, and multiple races), transmission category (men who have sex with men [MSM], injection drug use [IDU], MSM and IDU [MSM/IDU], high-risk heterosexual contact, and other), CD4 result, VL result, and OI information. All analyses adjusted for reporting delays and missing risk factor information [4, 5].

Methods for the enhanced collection of data included: a) updating data in the surveillance software from existing auxiliary laboratory databases, b) strengthening active surveillance efforts through increased medical record abstraction of laboratory data, c) identifying and collecting data from laboratories not previously reporting to HIV surveillance, and d) increasing the number of laboratory reports being sent to the surveillance programs electronically. Enhanced medical record abstraction was conducted up to 6 months following the 12-month diagnosis period using the Adult HIV Case Report Form. Electronic and paper-based laboratory results received up to 6 months after the 12-month diagnosis period and all medical record data were entered into the surveillance software and transferred to CDC as part of routine reporting of national HIV surveillance data. Although there may have been differences in how reports were transmitted and collected across the states (e.g., passive transmission of paper or electronic reports from laboratories *vs* medical record abstraction), the goal was for each health department to receive all HIV-related laboratory data.

We determined the distribution of stage of disease at diagnosis based on CD4 results or OIs within 3 months of diagnosis and the number and percentage of persons diagnosed with HIV who were linked to care within 3, 6, and 12 months based on CD4 and VL tests within these time frames. We also determined the number and percentage of persons diagnosed with HIV who were linked to care within 3 months by demographic and transmission categories. Finally, we determined the OIs diagnosed within 3 months of HIV diagnosis overall and by level of immune-suppression (CD4 count $\geq$200 cells/µL or $\geq$14%, and <200 cells/µL or <14%).

To assess the impact of enhanced data collection, we compared the project data on two measures (stage of disease and linkage to care) with (1) data from the same five states on cases diagnosed within 12 months prior to the initiation of the project (population A), and (2) data from 25 states on cases diagnosed during April 2005 through March 2006 (population B). The 25 states were selected for the analysis because they met the criteria outlined in the Technical Guidance for HIV/AIDS Surveillance Programs of at least 50% of newly diagnosed persons having an initial CD4 or VL result within 3 months of diagnosis reported to the national HIV surveillance system. Population B did not include any of the states with enhanced data collection.

SAS software version 9.1 (SAS Institute., Cary, NC) was used to perform univariate and bivariate analyses with the X^2 test. Chi-square p-values less than or equal to 0.05 were considered significant. To describe the completeness of data, we included all cases whether or not they were alive at the end of the observation period.

RESULTS

Of the 3,065 persons diagnosed during the 12-month diagnosis period in the five states, 9.6% were diagnosed with stage 1, 29.1% with stage 2, and 35.5% with stage 3 disease; 25.8% were stage unknown (Table 1A). The proportion of persons who had a result from at least one CD4 or VL increased as more time was allowed for tests to be performed

Table 1A. Stage of HIV Infection Based on CD4 Test[a] Performed within 3, 6, and 12 Months Following HIV Diagnosis Among Adults and Adolescents in 5 States[b] with Enhanced Data Collection, 2005-2006

	≤3 mo		≤6 mo		≤12 mo	
	No.	(%)	No.	(%)	No.	(%)
Stage 1	295	9.6	329	10.7	359	11.7
Stage 2	891	29.1	968	31.6	1,031	33.6
Stage 3 (AIDS)	1,087	35.5	1,120	36.5	1,155	37.7
Stage unknown	791	25.8	648	21.2	521	17.0
Missing CD4 collection date	1	0	0	0	0	0
Total	3,065	100	3,065	100	3,065	100

Table 1B. Stage of HIV Infection Based on CD4 Test[a] Performed within 3, 6, and 12 Months Following HIV Diagnosis Among Adults and Adolescents in 5 States Before Enhanced Data Collection (Population A[c]), 2004-2005

	≤3 mo		≤6 mo		≤12 mo	
	No.	(%)	No.	(%)	No.	(%)
Stage 1	331	7.6	374	8.5	409	9.3
Stage 2	1,027	23.4	1,149	26.2	1,271	29.0
Stage 3 (AIDS)	1,465	33.4	1,531	35.0	1,586	36.2
Stage unknown	1,556	35.5	1,326	30.3	1,113	25.4
Missing CD4 collection date	0	0	0	0	0	0
Total	4,379	100	4,379	100	4,379	100

Table 1C. Stage of HIV Infection Based on CD4 Test[a] Performed within 3, 6, and 12 Months Following HIV Diagnosis Among Adults and Adolescents in 25 States without Enhanced Data Collection (Population B[d]), 2005-2006

	≤3 mo		≤6 mo		≤12 mo	
	No.	(%)	No.	(%)	No.	(%)
Stage 1	952	9.0	1,051	9.9	1,152	10.8
Stage 2	2,104	19.8	2,305	21.7	2,518	23.7
Stage 3 (AIDS)	3,412	32.1	3,575	33.6	3,743	35.2
Stage unknown	4,161	39.1	3,699	34.8	3,217	30.3
Missing CD4 collection date	2	0	1	0	1	0
Total	10,631	100	10,631	100	10,631	100

[a]The lowest CD4 count or percentage taken from the time period of interest.
[b]Colorado, Indiana, Louisiana, Michigan (diagnosed between April 1, 2005 through March 31, 2006) and New York (diagnosed between June 1, 2005 and May 31, 2006).
[c]Population A: Colorado, Indiana, Louisiana, Michigan (diagnosed between April 1, 2004 through March 31, 2005) and New York (diagnosed between June 1, 2004 and May 31, 2005).
[d]Population B: Persons diagnosed with HIV in 25 states that had ≥50% of persons newly diagnosed between April 1, 2005 and March 31, 2006 with an initial CD4 or VL result collected ≤3 months of HIV diagnosis and reported to the national HIV surveillance system.

and reported (Table 2A); however, the majority (78.5%) had at least one CD4 or VL test within 3 months of diagnosis. Additionally, we assessed the impact of CD4 and VL tests initiated at the time of testing. When we removed persons who had the same diagnosis date and CD4 or VL collection date, the percentage of persons with a CD4 or VL test within 3 months dropped to 69.3%, data not shown.

Blacks/African Americans were less likely to have a CD4 or VL test performed (73.6%) within 3 months of HIV diagnosis than whites (82.1%, $p<0.001$) (Table 3). Persons aged 13-29 were also less likely to have a CD4 or VL test performed (72.3%), as compared to persons aged 30 and above (30-39 years: 76.7%, 40-49 years: 83.2%, ≥50 years: 86.6%). Across the five states, there were significant differences in the percentage of persons with a result from at

Table 2A. CD4 (Count or Percentage) and Viral Load Results Reported within 3, 6, and 12 Months Following HIV Diagnosis Among Adults and Adolescents in 5 States with Enhanced Data Collection, 2005-2006

	CD4 Only		VL Only		CD4 and VL		No CD4 or VL		Total	≥1 CD4 or VL[b]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.[a]	No.	(%)
3 months	202	6.6	165	5.4	2,040	66.5	658	21.5	3,065	2,407	78.5
6 months	162	5.3	154	5.0	2,234	72.8	515	16.8	3,065	2,550	83.2
12 months	157	5.2	122	4.0	2,370	77.3	416	13.6	3,065	2,649	86.4

Table 2B. CD4 (Count or Percentage) and Viral Load Results Reported within 3, 6, and 12 Months Following HIV Diagnosis Among Adults and Adolescents in 5 States Before Enhanced Data Collection (Population A), 2004-2005

	CD4 Only		VL Only		CD4 and VL		No CD4 or VL		Total	≥1 CD4 or VL[b]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.[a]	No.	(%)
3 months	641	14.6	320	7.3	2,124	48.5	1,294	31.9	4,379	3,085	68.1
6 months	615	14.0	299	6.8	2,388	54.5	1,077	24.6	4,379	3,302	75.4
12 months	539	12.3	276	6.3	2,680	61.2	884	20.2	4,379	3,495	79.8

Table 2C. CD4 (Count or Percentage) and Viral Load Results Reported within 3, 6, and 12 Months Following HIV Diagnosis Among Adults And Adolescents in 25 States without Enhanced Data Collection (Population B), 2005-2006

	CD4 Only		VL Only		CD4 and VL		No CD4 or VL		Total	≥1 CD4 or VL[b]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.[a]	No.	(%)
3 months	2,550	24.0	797	7.5	4,594	43.2	2,685	25.3	10631[c]	7,941	74.7
6 months	2,321	21.8	822	7.7	5,094	47.9	2,390	22.5	10631[c]	8,237	77.5
12 months	2,010	19.0	809	7.6	5,721	53.8	2,086	19.6	10631[c]	8,540	80.4

Note. CD4 = CD4+ T-lymphocyte count (cells/μL) or percentage, VL = viral load (copies/mL).
[a]Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total
[b]Data in this column (≥1 CD4 or VL) are not included in the column total.
[c]Four cases did not have a CD4 or VL specimen collection date.

least one CD4 or VL test. The percentage of persons with a CD4 or VL test result also varied by the facility of diagnosis; 93.0% at adult HIV clinics to 52.9% at HIV counseling and testing sites. No significant differences were found between the percentage of persons with at least one CD4 or VL test result among males and females or across transmission categories.

The most frequently reported OI was *Pneumocystis jiroveci* pneumonia (PCP) (38.6%, 197/511), followed by Esophageal Candidiasis (16.4%, 84/511), and Wasting Syndrome (7.2%, 37/511) (Table 4). Of the 378 persons with an OI diagnosed within 3 months of HIV diagnosis, a larger percentage of OIs was found among persons with a CD4 result of <200 cells/μL or <14% (98.3%) as compared to persons with a CD4 result of ≥200 cells/μL or ≥14% (1.7%).

Enhanced data collection appears to have resulted in more complete data and therefore a more accurate measurement of stage of disease and linkage to care. The proportion of persons classified as stage unknown within 12 months of diagnosis was larger in the comparison populations, with 25.4% and 30.3% in Population A and B, respectively, compared to 17.0% among cases with enhanced data collection (Table 1). As the time between HIV diagnosis and the first CD4 test performed increased from 3 months to 6 and 12 months, the percentage of persons classified as stage unknown decreased in all populations.

Persons in the five states with enhanced data collection (Table 2A) were more likely to have at least one CD4 or VL test result at 12 months after diagnosis (86.4%) compared with persons in Population A (79.8%, p<0.001, Table 2B) or Population B (80.4%, p<0.001, Table 2C). Within 3 months of HIV diagnosis, 78.5% of persons with enhanced data collection had a result from at least one CD4 or VL test, as compared to 68.1% and 74.7% in Population A and B respectively. Persons in the five states were also more likely to have an OI reported to surveillance within 3 months of diagnosis during the time of enhanced data collection than during the previous year (Population A) (12.3% *vs* 10.6%, p=0.02), data not shown.

DISCUSSION

Enhanced collection of laboratory data through the utilization of data in existing databases, strengthened active surveillance efforts, the identification of labs not reporting to surveillance, and an increased number of electronic reports, improved the completeness of CD4, VL, and OI data in national HIV surveillance. Although no true standard was

Table 3. CD4 (Count or Percentage) and Viral Load Results Reported within 3 Months Following HIV Diagnosis Among Adults and Adolescents in 5 States with Enhanced Data Collection, by Selected Characteristics, 2005-2006

	CD4 Only	VL Only	CD4 and VL	No CD4 or VL	Total[a]	≥1 CD4 or VL[c]	≥1 CD4 or VL Chi-Square p-Value
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)[b]	No. (%)	
Sex							
Male	149 (6.8)	112 (5.1)	1,454 (66.1)	484 (22.0)	2,199 (71.7)	1,715 (78.0)	Reference
Female	53 (6.1)	53 (6.2)	586 (67.6)	174 (20.1)	866 (28.3)	692 (79.9)	0.25
Race/Ethnicity							
Black/African American	117 (8.0)	60 (4.1)	900 (61.5)	386 (26.4)	1,463 (47.7)	1,077 (73.6)	< 0.001
Hispanic/Latino	18 (5.1)	16 (4.5)	267 (73.6)	61 (16.9)	362 (11.8)	301 (83.1)	0.99
White	51 (4.8)	75 (7.1)	755 (71.3)	179 (16.9)	1,059 (34.6)	880 (82.1)	Reference
Multiple races/Other race[d]	16 (8.8)	14 (7.7)	118 (65.4)	33 (18.1)	181 (5.9)	148 (81.9)	0.69
Age							
13-29	49 (5.3)	45 (4.8)	575 (62.1)	257 (27.7)	926 (30.2)	669 (72.3)	0.03
30-39	56 (6.3)	50 (5.6)	579 (64.9)	208 (23.3)	893 (29.1)	685 (76.7)	Reference
40-49	62 (7.6)	44 (5.4)	571 (70.3)	136 (16.8)	813 (26.5)	677 (83.2)	< 0.001
≥50	34 (7.9)	27 (6.2)	315 (72.5)	58 (13.4)	434 (14.2)	376 (86.6)	< 0.001
Transmission Category							
Male Adult or Adolescent							
Male-to-male sexual contact	86 (5.5)	79 (5.0)	1058 (67.5)	344 (21.9)	1,567 (71.3)	1,223 (78.1)	Reference
Injection drug use	23 (11.8)	8 (4.4)	116 (60.7)	44 (23.1)	191 (8.7)	147 (76.9)	0.71
Male-to-male sexual contact and injection drug use	17 (10.8)	5 (3.4)	103 (66.3)	30 (19.5)	156 (7.1)	126 (80.5)	0.49
Heterosexual contact[e]	21 (7.6)	18 (6.4)	171 (62.1)	66 (24.0)	275 (12.5)	209 (76.0)	0.45
Other	2 (21.6)	1 (14.7)	6 (62.6)	0	10 (0.4)	10 (100.0)	[f]
Female Adult or Adolescent							
Injection drug use	12 (7.2)	14 (8.3)	118 (69.1)	26 (15.4)	171 (19.8)	145 (84.6)	0.07
Heterosexual contact	39 (5.8)	39 (5.7)	458 (67.0)	148 (22.4)	684 (79.0)	536 (77.6)	Reference
Other	1 (13.5)	0	9 (82.6)	0	11 (1.2)	11 (100.0)	[f]
Project Area							
Colorado	24 (5.3)	16 (3.6)	338 (76.7)	63 (14.3)	440 (14.4)	377 (85.7)	< 0.001
Indiana	28 (5.9)	19 (4.1)	307 (65.5)	114 (24.4)	468 (15.3)	354 (75.6)	0.61
Louisiana	89 (10.0)	30 (3.3)	568 (63.5)	208 (23.2)	895 (29.2)	687 (76.8)	Reference
Michigan	41 (7.6)	17 (3.2)	327 (60.6)	154 (28.6)	540 (17.6)	386 (71.4)	0.02
New York	20 (2.7)	83 (11.5)	500 (69.3)	119 (16.5)	722 (23.5)	603 (83.5)	< 0.001
Facility of Diagnosis							
Private physician/HMO	20 (4.2)	30 (6.3)	346 (73.1)	78 (16.5)	474 (15.5)	396 (83.5)	0.08
Emergency room/Inpatient clinic	87 (13.3)	27 (4.2)	457 (69.7)	84 (12.9)	656 (21.4)	571 (87.1)	Reference
Adult HIV clinic	10 (8.0)	6 (5.0)	104 (79.8)	9 (7.2)	130 (4.2)	120 (93.0)	0.008
HIV counseling and testing site	18 (5.2)	13 (3.7)	151 (44.0)	161 (47.1)	342 (11.2)	181 (52.9)	<0.001
STD clinic	14 (11.4)	2 (1.8)	54 (45.1)	50 (41.7)	119 (3.9)	69 (58.3)	< 0.001
Correctional facility	4 (4.1)	4 (4.2)	66 (65.0)	27 (26.6)	102 (3.3)	75 (73.4)	0.01
Other clinic	17 (4.0)	20 (4.9)	230 (55.1)	150 (36.0)	417 (13.6)	267 (63.9)	<0.001
Unknown	32 (3.9)	62 (7.6)	633 (76.7)	98 (11.9)	825 (26.9)	727 (88.1)	0.02
Total	**202 (6.6)**	**165 (5.4)**	**2,040 (66.6)**	**659 (21.5)**	**3,065**	**2,406 (78.5)**	

Note. CD4 = CD4+ T-lymphocyte count (cells/μL) or percentage, VL = viral load (copies/mL).
[a]Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total
[b]The total percent represents the column percent.
[c]Data in this column (≥1 CD4 or VL) are not included in the column total.
[d]Other race: American Indian/Alaska Native, Asian, or Native Hawaiian/Other Pacific Islander.
[e]Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.
[f]The Chi-square test is invalid due to small cell size.

available for comparison, the percentages of persons diagnosed with HIV who had stage of disease assigned or who were linked to care were up to 10% higher with the enhanced data collection.

Table 4. Opportunistic Illnesses Reported within 3 Months Following HIV Diagnosis Among Adults and Adolescents in 5 States with Enhanced Data Collection, by CD4 Result, 2005-2006

	CD4 Count ≥200 Cells/μL or ≥14%		CD4 Count <200 Cells/μL or <14%		No CD4 Result		Total[a]
Overall OIs	No.	%	No.	%	No.	%	No.
OI within 3 months	6	1.7	372	98.3	0	0	378
OI with incomplete diagnosis date (missing mo.)	0	0	1	100	0	0	1[c]
No OI within 3 months	1,179	43.9	714	26.5	792	29.5	2,686
Total	1,185	1,087	792	3,065			
Individual OIs	No.	%	No.	%	No.	%	No.
Pneumocystis jiroveci pneumonia	1	0.5	196	99.5	0	0	197
Candidiasis, Esophageal	1	1.3	83	98.7	0	0	84
Wasting Syndrome	0	0	37	100	0	0	37
Candidiasis of Bronchi, Trachea, or Lungs	0	0	12	100	0	0	12
Cytomegalovirus Disease	0	0	26	100	0	0	26
Toxoplasmosis of Brain	3	14.3	19	85.7	0	0	22
Cryptococcosis	0	0	16	100	0	0	16
Histoplasmosis	0	0	14	100	0	0	14
M. tuberculosis, Disseminated or Extrapulmonary	0	0	12	100	0	0	12
Encephalopathy, HIV-related	0	0	11	100	0	0	11
Herpes simplex	0	0	11	100	0	0	11
Mycobacterium avium complex or M. kansasii	0	0	11	100	0	0	11
Kaposi's Sarcoma	0	0	16	100	0	0	16
Pneumonia, Recurrent	1	10.1	10	89.9	0	0	11
Cytomegalovirus retinitis	2	25.0	6	75.0	0	0	8
M. tuberculosis, Pulmonary	0	0	6	100	0	0	6
Lymphoma, Immunoblastic	0	0	4	100	0	0	4
Lymphoma, Burkitt's	0	0	3	100	0	0	3
Cryptosporidiosis	0	0	3	100	0	0	3
Coccidiodomycosis	0	0	2	100	0	0	2
Lymphoma, Primary, of Brain	0	0	2	100	0	0	2
Mycobacterium, Other Species	0	0	2	100	0	0	2
Progressive Multifocal Leukoencephalopathy	0	0	1	100	0	0	1
Total[b]	8	1.6	503	98.4	0	0	511

Note. CD4 = CD4+ T-lymphocyte count (cells/μL) or percentage.
[a]The following OIs were not represented in this population: Cervical Cancer (Invasive), Isosporiasis, Salmonella Septicemia (adult only).
[b]The total individual OIs do not add up to the total OIs (n=378), as some cases were diagnosed with more than one OI
[c]One case had a missing CD4 specimen collection date and could not be categorized by CD4 result.

The collection of more complete data provides a more accurate picture of disease severity and linkage to care. Based on CD4 and VL laboratory tests performed within 3 months following diagnosis, we estimated that 78.5% of persons diagnosed in the five states were linked to care. This finding is somewhat higher than what was observed through an analysis of persons newly diagnosed with HIV infection in New York City, where the time between the first positive Western blot test and the first CD4 and/or VL result reported to surveillance was used to indicate the time period from the initial HIV diagnosis (non-AIDS) to the first HIV-related medical care visit [6]. Of 1,928 newly diagnosed persons in New York City in 2003, an estimated 63.7% initiated care within 3 months of diagnosis.

Overall, linkage to care needs strengthening to reach the goal outlined in the National HIV/AIDS Strategy of 85% of newly diagnosed patients linked to clinical care within 3 months of diagnosis [7]. We found a significantly higher proportion of persons with no CD4 or VL test results among blacks/African Americans as compared to whites which suggests that a racial disparity may exist among newly diagnosed persons who receive care. This finding is consistent with other studies that have documented an

association between racial factors and disparities in HIV-related healthcare [8-11] and may be related to a complex interaction between health care, public health, and social factors [12]. These data also show that younger persons aged 15-29 were less likely to have a CD4 or VL test, as compared to persons aged 30 and above. The disparity seen in age may be a function of the large proportion of young adults that are uninsured [13], and serves to highlight the potential gap in accessing care between age groups. Additional interventions are needed to meet the goals of the National HIV/AIDS Strategy on linkage to care and the reduction of HIV-related disparities.

The initiation and frequency of laboratory testing and interpretation of laboratory results can be used to make inferences about the quality of health care that HIV-infected persons receive. Laboratory testing that occurs shortly after HIV diagnosis implies the successful linkage to health care. Serial CD4 and VL testing suggests utilization of ongoing care compared with a one-time visit. If the frequency of serial laboratory tests meet clinical management testing guidelines (e.g., every 3-4 months after initial diagnosis baseline measurement), it suggests receipt of higher quality care than less frequent laboratory testing would.

Persons without CD4 or VL testing following HIV diagnosis may represent persons with unmet healthcare needs. To address unmet healthcare needs and develop effective interventions, it is important to understand the barriers to accessing care such as lack of health insurance coverage [14, 15], unsuccessful patient notification of positive HIV test results [16-18], denial, poverty, mental illness, lack of transportation, and homelessness [19-21]. States have a responsibility to provide unmet health care need estimates to the Health Resources and Services Administration (HRSA), which oversees the Ryan White CARE Act. Surveillance data could be used to provide estimates of persons not in care and, therefore, assist states in meeting this federal reporting obligation.

OI data can be a useful indicator of clinical outcomes for HIV-infected persons in care. Based on OI data reported within 3 months following diagnosis, we estimated that 12.3% of persons diagnosed in the five states had at least one OI; PCP was the most frequently reported. A similar finding was observed through an analysis of a population-based survey of persons in HIV-related medical care in King County Washington, selected health districts in Louisiana, and the state of Michigan [22]. Of all HIV-infected persons in care in these areas in 1998, 11.3% (CI, 8.8–13.9) had at least one OI diagnosis and PCP was the most commonly diagnosed.

There are some limitations to consider when interpreting our findings. First, if laboratory data reported to surveillance are incomplete, the methods outlined may underestimate the prevalence of persons with access to medical care. In addition, the contribution of individuals who may be diagnosed in a jurisdiction reported to a state HIV program but then leave the state is unknown. From the local surveillance perspective, these individuals may not have begun care (i.e., evidence of lab testing) but received care after they moved out of jurisdiction. In Louisiana, the number of cases reported to surveillance and the completeness of laboratory data collected after August 2005 was impacted by Hurricane Katrina, as several clinical sites were closed and complete medical record abstraction was not possible.

In jurisdictions that have laws or regulations for laboratory reporting of all HIV-related tests, private and public laboratories must report all test results to the respective health departments. During the data collection period, changes in CD4 and VL reporting laws may have contributed to improvements seen in the completeness of laboratory reporting. For example, the laboratory reporting requirements were significantly broadened in New York State in June 2005, the start of the 12-month diagnosis period, to require the reporting of any VL result and all CD4 counts and percentages. Prior to this change, only detectable VLs and CD4 counts less than 500 cells/μL or percentages less than 29% were reportable. In July 2005, Michigan also revised their regulations to require the reporting of all CD4 and VL results.

In general, surveillance programs believe they are receiving the vast majority of HIV test results; but, unless a state is actively monitoring the number of laboratories reporting to them and the volume of reports, they cannot know for certain. Instances where laboratory testing may change (e.g., the provider decides to use another laboratory or the primary laboratory contracts with a new laboratory for specialized testing) may not necessarily be identified by a surveillance program. Active surveillance and medical record abstraction can help to obtain more complete laboratory data and identify laboratories that may not be reporting to HIV surveillance. The electronic transmission of HIV-related laboratory test results enhances the completeness, timeliness, and accuracy of reporting to surveillance programs [23]. Although many surveillance programs have received data electronically for years, many still need improvements or enhancements to implement and maintain the system. HIV surveillance programs are currently using software called eHARS that has the capacity for storage of all laboratory results and the ability for electronic laboratory data to be imported. To ensure that all laboratory results are reported to surveillance at the national level, state and local surveillance programs must ensure that all laboratory results, including those stored in auxiliary databases, are entered into eHARS software and transmitted to CDC.

The National HIV/AIDS Strategy proposes to reduce new HIV infections, increase access to care and improve health outcomes for people living with HIV, and reduce HIV-related disparities [8]. Data collected through the national HIV surveillance system can be used to monitor the outcomes of the national strategy; however the validity of these measures is dependent upon the completeness and quality of surveillance data. Monitoring outcomes such as linkage to care and racial/ethnic disparities among persons who are virally suppressed is particularly dependent upon complete reporting of all HIV-related laboratory results to surveillance.

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CONFLICT OF INTEREST

None of the authors have a reported financial, consultant, institutional or other conflict of interest in the publication of this manuscript.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official view of the Centers for Disease Control and Prevention

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NOTICE OF FINAL RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

COMPLETE REPORTING OF CD4 T-LYMPHOCYTE, VIRAL LOAD AND GENOTYPING TEST RESULTS RELATING TO HIV

28 PA. CODE §§ 27.1, 27.4, 27.21a, 27.22, 27.23, 27.32a-27.32e

The Department of Health (Department), with the approval of the Advisory Health Board, amends 28 Pa. Code §§ 27.21a, 22, 23, and 32a-32e (relating to communicable and noncommunicable diseases). The amendments are to read as set forth in Annex A.

I. PURPOSE AND BACKGROUND

This rulemaking amends the Department's requirements for the reporting of HIV infection. Those requirements, which had included the reporting of CD4 T-lymphocyte test results with a count of equal to or less than 200 cells/μL or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes, will now require the reporting of all CD4 T-lymphocyte cell counts and percentages relating to HIV infection, as well as the reporting of all viral load test results, including detectable and undetectable viral loads, and genotyping results related to HIV.

The Department added the reporting of cases of HIV infection and CD4 T-lymphocyte test results to its communicable and noncommunicable disease reporting regulations in 2002. At the time, it limited the required reporting of CD4 T-lymphocyte test results to those results at or below a certain count or percentage and did not require viral load or genotyping test result reporting at all. Since that time, the manner and ability to detect and treat persons with HIV and to suppress the virus in persons with the infection has changed and improved, and the need for complete reporting, and complete reporting of viral loads and genotyping as well as CD4 counts, has become apparent. The Centers for Disease Control and Prevention of the federal Department of Health and Human Services (CDC) has made it clear that reporting of all CD4 T-lymphocyte cell counts, viral loads, and genotyping test results related to HIV is essential to early and appropriate treatment. In order to stop the spread of HIV, prevent the emergence of

new cases, and keep those living with HIV healthy, the *National HIV/AIDS Strategy for the United States, updated for 2020*, has, as its critical foci, widespread testing and linkage to care, broad support for people living with HIV to remain engaged in comprehensive care, universal viral suppression among persons living with HIV, and full access to Pre-Exposure Prophylaxis (PrEP) services to prevent the spread of disease. *See National HIV/AIDS Strategy for the United States, updated for 2020* (July 2015), at Executive Summary 3, https://files.hiv.gov/s3fs-public/nhas-update.pdf. Accessed February 23, 2018 (hereinafter referred to as "*National HIV/AIDS Strategy*").

In order to achieve these goals, the CDC recommends, among other things, the reporting of all CD4 test results (counts and percentages) and all viral load results (undetectable and detectable specific values). *See Letter from Kenneth G. Castro, M.D., Assistant U.S. Surgeon General, U.S. Public Health Service and Amy Lansky, Ph.D., M.P.H., Deputy Director for Surveillance, Epidemiology and Laboratory Sciences, Division of HIV Prevention, CDC*, a copy of which is attached hereto as Exhibit "A". A letter directly to the former Secretary of Health, Karen Murphy, from the Director of the Office for State, Tribal, Local and Territorial Support and Deputy Director of the CDC, reiterated this position to the Commonwealth, as one of only 6[1] states that did not collect all CD4 test results. *See Letter from Jose T. Montero, M.D., MHCDS, Director, Office for State, Tribal, Local and Territorial Support and Deputy Director, Centers for Disease, Control and Prevention, and Jonathan A. Mermin, M.D., M.P.H, RADM and*

[1] At the time the letter was sent, the Commonwealth was one of six states that did not collect all CD4 test results. That number has since fallen to four. See *Email from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health (9/11/2018 10:56 AM)*, attached hereto as part of Exhibit "C."

Assistant Surgeon General, United States Public Health Services, and Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention to Secretary Karen Murphy, dated February 8, 2017 ("*Letter to Secretary Murphy*"), a copy of which is attached hereto as Exhibit "B". The letter stated the following:

> The updated National HIV/AIDS Strategy for the United States identifies primary goals to guide our collective national fight against HIV. The success in advancing several of these goals, ensuring sustained viral suppression for person living with HIV and measuring progress towards HIV care, relies on *laboratory reporting of HIV-related tests, including all CD4+ T-lymphocyte (CD4) and viral load test results, to local and national HIV surveillance systems*. Complete laboratory data are critical to identifying cases, measuring care and treatment outcomes, and measuring the effectiveness of public health interventions. Specifically, these data are often used to monitor disease progression, determine the stage of HIV infection, monitor receipt of HIV care and treatment, and make decisions about public health interventions. Both viral load and CD4 data are used to assess whether patients are responding to treatment: when treatment is successful, CD4 counts rise and viral loads fall. Current HIV clinical management guidelines call for CD4 and viral load testing at the time of diagnosis and regularly thereafter. When CD4 and viral load results are reported, public health agencies can determine access to care and treatment outcomes. For these reasons, CDC recommends complete state reporting of all HIV test results.

Letter to Secretary Karen Murphy, supra (emphasis added).

At the present time, Pennsylvania is one of only four states that do not collect all CD4 T-lymphocyte test results. *See Email from Richard Selik (CDC/OID/NCHSTP) to Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health (9/11/2018 10:56 AM),* attached hereto as part of Exhibit "C." In addition, of the 50 states, only Pennsylvania and Idaho fail to require the reporting of all viral load test results. *See Email from Dr. Richard Selik (CDC/OID/NCHSTP) to Dr. Godwin Obiri, Epidemiology Supervisor, Bureau of Epidemiology, Pennsylvania Department of Health* (2/28/2018 12:24 PM), attached hereto as part of Exhibit "C". In order to appropriately protect the public's health by suppressing the

spread of HIV, and provide better, more effective treatment for persons living with HIV, the Department is amending its regulations to require complete reporting.

The Department is also taking this step to ensure that, if, in the future, public funding is tied to disease burden, as has been suggested could occur, the Commonwealth will not be disadvantaged. Goal 1 of the National HIV/AIDS Strategy, which calls for reducing new HIV infections, *see National HIV/AIDS Strategy* at 1, sets forth as a recommended action the allocation of public funding consistent with the geographic distribution of the epidemic. *Id.* at 19. The *National HIV/AIDS Strategy* recommends a similar action with regard to Goal 4, achieving a more coordinated national response to the HIV epidemic. *Id.* at 43; *see also* 45 ("The Federal government should review the methods used to distribute Federal HIV funds and take steps to ensure that resources go to the States and localities with the greatest burden of disease.") If, in the future, federal funding is tied to disease burden, the Commonwealth would be at a disadvantage among other states with more complete verifiable data. *See* Exhibit "B".

II. SUMMARY AND OVERVIEW OF GENERAL COMMENTS

The Department received four letters of comment on its proposed rulemaking in addition to comments from the Independent Regulatory Review Commission (IRRC), one opposed, and three in support.

Comments Supporting the Rulemaking

Three commentators supported the Department's proposed rulemaking. Dr. Thomas A. Farley, the Health Commissioner of the City of Philadelphia, stated that Office of the Health

Commissioner of the City of Philadelphia was in "full support" of the Department's proposed regulations. He stated that the spread of HIV was a serious issue, pointed out that the Commonwealth was one of only four states not mandating reporting of all CD4 percentages and counts, and one of only two not requiring all viral load test results. Dr. Farley also referenced the *National HIV/AIDS Strategy* and stated that the ability to meet the goals set out in that document depended upon comprehensive reports of all HIV-related tests. He noted that the City of Philadelphia already requires reporting of all CD4 and viral load test results. He stated that this allows the City to better track the epidemic, focus resources based on the needs of the impacted communities and improve the health of the City's residents. He stated that the Department's regulation would help to ensure persons living with HIV (PLWH) have access to care and are engaged in care and virally suppressed, facilitate the monitoring of the HIV epidemic in the Commonwealth, and bring HIV reporting in the Commonwealth in line with national standards.

The Community Co-Chair of the Pennsylvania HIV Planning Group provided a letter of support stating that he hoped that the Department's proposed regulation would be adopted, because the regulation would allow the pinpointing and accurate reporting of the epidemic in the Commonwealth and would allow the analysis of trends that would help to target treatment and prevention efforts. He stated that "[this] information is the primary base for all planned activities [aimed at ending the epidemic in Pennsylvania]."

Finally, ViiV Healthcare, a pharmaceutical manufacturer of HIV medicines, commented in support of the proposed rulemaking. The Director of Government Relations of that company

stated that it was devoted exclusively to supporting the needs of persons living with or affected by HIV, and that its singular focus was to improve their health and quality of life. He also stated that advances in the treatment of the disease has transformed HIV from a terminal illness to a manageable chronic condition, that effective treatment could help PLWH live longer, healthier lives, and that effective HIV treatment could prevention transmission of disease. He cited a recent study in the British Journal, The Lancet, which found that when trading the HIV-positive partner in a serodiscordant couple with antiretroviral therapy, there were no linked infections observed with the infected partners HIV viral load was below the limit of detection. *See* Rodger A.J., *et al.*, "Risk of HIV Transmission through Condomless Sex in Serodifferent Gay Couples with the HIV-Positive Partner Taking
Suppressive Antiretroviral Therapy (PARTNER): Final Results of a MultiCentre Prospective, Observational Study," The Lancet, (Published online May 2, 2019) http://dx.doi.org/10.1016/S0140-6736(19)30418-0. He went on to comment that an important component of public health initiatives, including U=U (Undetectable = Untransmittable), is that policy makers have access to performance related data indicating the quality of health care in order to promote and achieve viral suppression goals and to assist the Department to better identify and target funding programs. He noted that if federal funding decisions become based on states that can demonstrate the greatest disease burden, the Commonwealth will lose a significant portion of valuable federal dollars, because it will only be reporting a portion of the total HIV population. He encouraged the adoption of the proposed amendments because the Commonwealth would then be brought into alignment with the reporting requirements of the majority of other states, and would be better able to track new cases, monitor clinical results and

make program decisions that would have the greatest impact on the lives of PLWH in the Commonwealth.

The Department appreciates the support of the City of Philadelphia, which has the highest HIV disease burden in the Commonwealth. The Department also thanks the HPG Committee for its support, particularly given its experience, and its knowledge of the funding decisions and issues facing the Commonwealth and the need for accurate data to inform those decisions to ensure the funding received targets the epidemic appropriately and effectively. Finally, the Department agrees with and echoes the comments of ViiV, particularly in regard to the need for accurate and complete data to ensure that PLWH are referred to treatment early, so that they may receive the most effective treatment, HIV transmission may be checked, and the spread of new infections blocked.

In addition, the Department is in agreement with the concerns expressed by ViiV regarding the risk of losing federal dollars if federal funding were to be targeted at states that can demonstrate the greatest burden of disease, and the Commonwealth were to lack the requirement for complete reporting that is created by this rulemaking. Such an action is not beyond the realm of possibility; it would be in line with changes made to the CARE Act at the time the Department made HIV reportable by name in the Commonwealth, almost the last state in the country to take that action. At that time, the federal agency that provides funding for HIV/AIDS services, the Health Services Resource Administration (HRSA), changed its rules to condition the apportionment of state funding upon the number of live HIV cases within a jurisdiction, rather than live AIDS cases, based on changes to the CARE Act. *See The Ryan White CARE Act: A*

Side-by Side Comparison of Prior Law to the Newly Reauthorized CARE Act, The Henry J. KAISER FAMILY Foundation, December 2006, at 3 (https://www.kff.org/wp-content/uploads/2013/01/7531-03.pdf), accessed October 28, 2019. Although the enforcement of this formula was delayed some years, HRSA eventually required all states to institute name-based HIV reporting in order to meet the level of accuracy for the data demanded to support a fiscal claim by the state. *Id.*, *see also* HIV Prevalence Estimates – United States, 2006, MMWR 57(39);1073-1076 October 3, 2008), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a2.htm , accessed October 28, 2019. A similar circumstance could arise here, and states with more reliable data could receive the bulk, potentially all, of available federal funding.

Comments Opposed to the Rulemaking

One commentator raised concerns that the Department's requirement to include hospitals among the reporters of all CD4 T-lymphocyte counts, viral loads and genotype testing was duplicative, and costly in time and money for a hospital, particularly when reference laboratories are providing these reports. IRRC echoed this comment and has requested that the Department explain how the regulated community is to use the electronic reporting system, and that the Department work with the community to ensure they understand how the system will work, and the reporting options open to them.

The Department has not changed the requirements of the regulations that multiple persons report these, as well as all reportable diseases, infections and conditions listed in 28 Pa. Code Chapter 27. The Department has received similar comments before when it has attempted to revise and

update its reporting regulations. It considered and responded to the question of duplicative reporting when it last updated its regulations relating to communicable and noncommunicable diseases in 2002 (*see Reporting of Communicable and Noncommunicable Diseases*, 32 Pa.B. 491 (January 26, 2002) https://www.pabulletin.com/secure/data/vol32/32-4/32-4.pdf, accessed October 28, 2019) and when it added the requirement that HIV test results, certain CD4 T-lymphocyte test results, and perinatal test results should be reported to the Department by name later that same year. *See Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV*, 32 Pa. B. 3597, 3602 (July 20, 2002) https://www.pabulletin.com/secure/data/vol32/32-4/161.html, accessed October 28, 2019. The Department's response then remains relevant today:

> With respect to issues involving the requirement of multiple reporters, the Department requires reporting from all different types of reporters, including practitioners, facilities, laboratories, other providers and the public for several reasons. The Department does not want possible reporters to self-censor, based on their assumption that another person will make the report. That could lead to under-reporting, and jeopardize the ability of the public health system to positively impact the health of infected individuals and their contacts. If the Department and local health departments are unaware of cases, they will be unable to offer or provide follow-up, including counseling and referral information, and perform case investigation.
>
> The Department also receives different information from different reporters. For example, a report by a laboratory is a confirmatory report of a disease or condition diagnosed by a health care practitioner. From heads of institutions the Department will receive information that is neither a diagnosis nor a confirmed report, but a suspicion that may help to identify a disease outbreak. The monitoring of the disease in the patient is dependent on receiving information from a practitioner as well as a laboratory, as is the monitoring of the disease in the population as a whole. Information relating to opportunistic infections, referrals, mode of transmission and treatment are not shared by a practitioner with the laboratory, and, therefore, the Department would not be able to obtain this type of specific information from laboratories if laboratories alone were to report. A provider would not release this type of information to a laboratory because of its confidential nature. A laboratory does not need to be aware of the mode of transmission of a disease or types of referrals made for the individual to perform its licensed function--conducting laboratory tests of specimens.

> The more specific the information received by the Department from all reporters, the more likely it is that the Department will be able to match information obtained from other sources, sometimes incomplete, and obtain complete information on each reported case. The more complete the demographic picture of the individual whose results are being reported, the easier it is for the Department to track the disease in this Commonwealth for purposes of implementing prevention measures, including targeting funding to affected populations. Further, the more complete the information on a specific individual the Department obtains, the easier it becomes for the Department and local health departments to provide follow-up services to that individual. For example, with a case of infectious tuberculosis, the Department will provide treatment, including directly observed therapy, to ensure that the case is cured, and will also locate and test and treat contacts as necessary. In the case of sexually transmitted diseases, the Department and local departments locate and offer counseling and testing services to partners of individuals who test positive.

Reporting of Communicable and Noncommunicable Diseases, 32 Pa.B. at 492-493. At that time, and for those reasons, the Department declined to change the proposed regulations, which were ultimately approved as final without change, and implemented. They have been in effect for at least 17 years. Therefore, all existing hospitals, laboratories, other health care providers and practitioners should be supplied with the appropriate credentials to report the listed reportable diseases electronically and should be reporting regularly as required by law. The Department is simply asking providers and laboratories to report all rather than some of the CD4 counts and percentages already being reported and has added reporting of viral loads and genotype testing relating to HIV to the existing list.

In addition, the National HIV/AIDS Strategy acknowledges the need for duplicate reporting, stating: "Surveillance necessitates a complex system of reporting from providers, laboratories, and State and local health departments to coordinate accurate, complete, and timely reporting." *See National HIV/AIDS Strategy*, at 46. The Department again declines to limit the types and number of entities required to report, in the interest of ensuring the most complete reporting that can be achieved. Forty-six states mandate reporting of all CD4 and viral load tests, and many of

those states ask for reporting by both laboratories and providers. This requirement, therefore, is within the bounds of accepted public health practices.

IRRC asked that the Department explain to the regulated community how the system is to work. Reports are sent to the Department's electronic disease surveillance system through either manual key entry, or, in the case of some laboratories, through electronic batch reporting to the Department's electronic laboratory reporting system. In considering the issue of manual reporting, the Department reviewed data relating to reporting of CD4 and viral load test results from 2016-2019. Of the 175,965 HIV-related reports submitted by hospitals and laboratories to the Department, only 9,277, or roughly 5%, were reported manually. The data show that hospitals and laboratories that report a relatively small volume of cases are the entities that are reporting by manual entry. Hospital laboratories and commercial laboratories with larger volumes are more likely to report through batch reporting to the electronic laboratory reporting system. Once the parameters for sending data are updated, adding more reports to electronic feeds does not pose an ongoing burden to the laboratory. The Department is continuing to work with laboratories that are interesting in sending data through the electronic laboratory reporting system; however, some laboratories prefer manual reporting because they feel that the resources needed to report manually are less than those needed to establish electronic batch reporting.

With respect that request that the Department explain the system to reporters, however, the Department would also note that most reportable diseases, infections and conditions have been reportable electronically since 2002, and that HIV was made reportable electronically by notice as provided for in the HIV reporting regulations in 2006. At the time electronic reporting was

first implemented, some 17 years ago, the Department reached out to reporters, and conducted trainings and provided access to its electronic disease surveillance system. The regulated community has been using the existing electronic disease surveillance system and reporting diseases, including those CD4 T lymphocyte cell counts equal to or less than 200 cells/μL, or less than 14% of total lymphocytes for 13 of those 17 years. To the extent any member of the regulated community has questions regarding the Department's current electronic disease surveillance system and its use, the Department provides a number and a contact person to whom questions may be addressed, and help sought, when new reporters are credentialed to use the system.

The Department is sensitive to cost concerns of its reporters. The Department, however, must view the resources, time, and costs needed for reporting in the context of the need to monitor and promote the health of the citizens of the Commonwealth,. With respect to HIV, there is an urgent public health need to monitor the proportion of cases under care and the proportion of cases adequately treated. Adequate treatment improves the health of persons with HIV and reduces their need for more expensive medical interventions. Furthermore, at least four clinical trials published since 2016 have demonstrated that adequate treatment of cases (indicated by low or non-existent viral loads and normal CD4 counts) dramatically reduces transmission of HIV. *See* Rodger A.J., Cambiano V., Bruun T., *et al.*, "Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy," *JAMA*. 2016;316(2):171–181, DOI:10.1001/jama.2016.5148 (July 12, 2016) (https://jamanetwork.com/journals/jama/fullarticle/2533066), accessed October 28, 2019; Cohen

M.S., Chen Y.Q., McCauley M., *et al.*, "Antiretroviral Therapy for the Prevention of HIV-1 Transmission," NEW ENG. J. MED. 2016; 375:830-839. DOI:10.1056/NEJMoa1600693 (September 1, 2016) (https://www.nejm.org/doi/full/10.1056/NEJMoa1600693), accessed October 28, 2019; Bavinton B.R., Pinto A.N., Phanuphak N., *et al.*, "Viral Suppression and HIV Transmission in Serodiscordant Male Couples: an International, Prospective, Observational, Cohort Study," *The Lancet HIV 2018*; 5(8): e438-e447 (July 16, 2018) (https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(18)30132-2/fulltext), accessed October 28, 2018; Rodger A.J., Cambiano V., Bruun T., *et al.*, "Risk of HIV Transmission through Condomless Sex in Serodifferent Gay Couples with the HIV-Positive Partner Taking Suppressive Antiretroviral Therapy (PARTNER): Final Results of a Multicentre, Prospective, Observational Study," *The Lancet 2019*; 393(10189): P2428-2438 (June 15, 2019) (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30418-0/fulltext), accessed October 28, 2019.

Identifying populations or areas with substandard levels of treatment could lead to interventions, such as improving linkage to care in underserved populations, that could eventually significantly reduce the Commonwealth's burden of HIV. In 2010 dollars, the lifetime treatment cost of one HIV case is approximately $379,668.00. https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html. Prevention of new cases, by, among other things, continuing existing cases in treatment and suppressing viral load is an obvious cost savings to the Commonwealth. The cost savings of a case of HIV averted has been estimated at between $ 20,000 to $100,000 per case. *See* Woodak and Cooney, "Do Needle Syringe Program Reduce HIV Infection Among Injecting Drug Users: A

Comprehensive Review of the International Evidence," *Substance Use & Misuse*, Vol. 41, 2006 (Issue 6-7) at 20-22; *see also* "Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users," *(Evidence for Action Technical Papers) World Health Organization (2004) ("WHO White Paper")*, at 15-16. The Commonwealth saw 991 new cases of HIV in 2016. Pennsylvania Department of Health, *Annual HIV Surveillance Summary* (2016) http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/E-H/HIV%20And%20AIDS%20Epidemiology/Documents/Pennsylvania%202016%20Annual%20HIV%20Surveillance%20Report.pdf, accessed July 2, 2018. Using these figures, the cost to the Commonwealth of those 991 cases could be as high as $376,250,998.00. Preventing them from occurring could be a savings of as much as $99,100,000. Although determining the actual cost that the proposed rulemaking will impose on providers and laboratories is not possible, it is extremely unlikely that this cost would outweigh the benefits of eventually improving the health of persons infected with HIV and decreasing the number of new cases of HIV.

Comments Relating to Specific Sections

Section 27.4. Reporting of cases.

IRRC raised several issues with sections of the Department's regulations relating to communicable and noncommunicable diseases that the Department had not originally included in the proposed rulemaking. Section 27.4, relating to reporting generally, is one of those sections. IRRC specifically references Section 27.4(a) and (e), relating to reporting cases, and points out that the references to a forthcoming implementation of an electronic system in Section 27.4(b) are outdated. In fact, those references did refer to the implementation of PA-NEDSS which occurred sometime after those regulations were promulgated in 2002. In addition, IRRC

points out that Section 27.4(e) included references to multiple methods of reporting, which could cause confusion and raise issues of clarity. IRRC asks that the Department explain to the regulated community what reporting options are available, and suggested that the final regulation be amended to reference other options for reporting, if paper reporting is acceptable.

In reviewing IRRC's comments, and the language in Section 27.4, the Department has determined that clarification of electronic versus paper reports is appropriate, and revisions to that section eliminating language that is outdated to specifically capture current reporting requirements is within the scope of the final rulemaking. The Department has therefore made amendments to that section in order to clarify how reports are required.

By way of background, under current law and regulations, and not altered by this rulemaking, reporters have a duty to report to the Department, and to report in the format required by the Department. 35 P.S. § 521.4. The Department first required electronic reporting of reportable diseases, infections, and conditions in a rulemaking published in the *Pennsylvania Bulletin* on January 26, 2002. *See Reporting of Communicable and Noncommunicable Diseases*, 32 Pa.B. 491 (Jan. 26, 2002). In order to provide enough time for reporters other than laboratories to prepare for electronic reporting, (laboratories were required to report electronically immediately upon that rulemaking's publication), the Department, in Section 27.4, set the implementation date of the electronic reporting requirement for most diseases, infections and conditions for six months after notice was published in the *Pennsylvania Bulletin*. See 28 Pa. Code § 27.4(b). Because that language is no longer applicable, and electronic reporting has long been in place in the Commonwealth, the Department has deleted this language from Section 27.4(b).

The Department, however, exempted HIV, AIDS, CD4-T-lymphocyte test results for counts less than 200 cells/μL of less than 14% of total lymphocytes and perinatal exposure of a newborn, from electronic reporting under that Notice. The Department did not make those diseases, infections and conditions reportable until six months after publication of a second notice on November 4, 2005. *See Electronic Reporting Requirements for Specified Diseases, infections and Conditions*, 35 Pa.B. 6192 (Nov. 4, 2005). The Department had waited several years after the institution of confidential HIV name-based reporting in 2002 to require electronic reporting of those specific items in order to ensure that certain data security requirements of the CDC were successfully met. By that date, the Department had required that reports of all reportable diseases, infections and conditions were to be made electronically. That requirement remains in place. Paper reporting is slow and inefficient and requires resources for processing and key entry that the Department does not have. Revisions to Section 27.4 included in this final rulemaking emphasize the Department's position.

The Department has also replaced concepts relevant to reporting in 2002 with language relevant to current electronic reporting requirements. References made to local morbidity reporting offices (LMROs) -- the Department's district offices and the county/municipal health departments that partner with it in its disease control functions – which were necessary to manage work when reporting was on paper, but meaningless in the context of electronic reporting, have been deleted. Subsection (c) has also been revised to remove references to hard copies and to the appropriate office being able to provide the form, since the form is now

electronic in nature, all reports are made into the electronic system, and access is obtained from the Department upon request. *See* 28 Pa. Code § 27.4(c).

The Department notes, however, that a preliminary case report by telephone is still acceptable, an early warning to the Department in effect, but formal reports with all the appropriate information that make disease surveillance and control possible must still be made through the appropriate electronic surveillance system. *See* Section 27.4(b).

The Department's interest is to obtain reports in a timely manner. Depending on the circumstances, a reporter may judge that some type of telephonic report is most appropriate. However, if a phone report is made, the reporter must still submit a formal case report to the appropriate surveillance system. As recommended, the Department has eliminated the language from Subsection (b) referencing the expectation that the electronic surveillance system will shortly be in place, and that reporters will be notified that electronic reporting has started. Subsection (e) has been re-designated as Subsection (c), and now refers to the content of the report as opposed to the method of reporting. The subsection makes it clear that assistance with reporting may be obtained by contacting the Department.

Section 27.22. Reporting of cases by clinical laboratories.

IRRC commented that Section 27.22(d) includes a reference to electronic mechanisms, which could potentially create confusion with other references to electronic disease surveillance systems. The Department notes that while the Department proposed to amend subsection (b) of Section 27.22, it did not propose revising Subsection (d), although it should have done so.

Section 27.22(d) did include a reference to CD4 T-lymphocyte counts and percentages and to HIV. That reference has now been deleted so that Subsection (d) will comport with the rest of the rulemaking. *See* 28 Pa. Code § 27.22(d).

At the time the regulatory amendment adding HIV and CD4 T-lymphocyte counts and percentages to Subsection (d) was promulgated in 2002, the Department had not yet made HIV cases reportable electronically. The CDC had heightened security requirements relating to electronic reporting and storage of HIV information, and it was not until the Department received approval from the CDC to allow electronic reporting of HIV in 2006 that laboratories and providers began to report electronically. The Department has revised Subsection (d) in this final rulemaking to remove the references to HIV and to CD4 counts and percentages, as well as the reference to the specific section governing HIV reporting, which was a necessary reference in 2002, but is no longer required under the existing reporting requirements. The remainder of the diseases and conditions listed in Subsection (d) are still reported through mechanisms delineated in the specific sections referenced in that subsection. The Department has also replaced the term "secure electronic mechanisms," with "electronic disease surveillance systems," to reflect the actual operations of the Department, and for the sake of consistency in the language of the regulation.

Section 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and nondetectable viral load results and genotype test results, and perinatal exposure of newborns to HIV.

IRRC had several comments on this section. IRRC suggested that, because the Department refers to the electronic reporting system as PA-NEDSS in the Preamble and in the Regulatory

Analysis form, the Department define "electronic disease surveillance system" in the regulations, and if appropriate, reference PA-NEDSS in that definition. The Department agrees that a definition of "electronic disease surveillance system" should be added and has added the term to Section 27.1 (relating to definitions). After considering whether to continue to reference PA-NEDSS, and whether to add the term to the definition section, the Department has decided that including the term would not be useful. While PA-NEDSS was the Department's first electronic disease surveillance system, the Department has different electronic data collection systems for different program areas as well as an electronic system for submission of batch laboratory data. In addition, the Department may, sometime in the future, change or rename its electronic disease surveillance system. Therefore, while the Department has provided a definition of "electronic disease surveillance system" that is broad enough to encompass all the systems that are used or will be used by the Department, including PA-NEDSS, the Department has chosen not to reference PA-NEDSS in the rulemaking. The definition also includes, for purposes of this rulemaking, electronic laboratory reporting systems. The Department has provided a definition for "electronic laboratory reporting system" to help with the understanding of that term.

IRRC has questioned the Department's use of the word, "shall," in this section, which makes reporting electronically mandatory, because the Department has stated that it will also accept paper reports. IRRC specifically referenced the regulation at 28 Pa. Code § 27.4 (relating to reports), which was not originally intended to be a part of this rulemaking. IRRC suggested that the final regulation be amended to reference other options for reporting, if paper reporting is acceptable. Although Section 27.4 was not originally included in the proposed rulemaking, the Department has considered IRRC's comments, and agrees, for the sake of clarity and in order to

update the regulations to reflect current practices, it has made revisions to that Section. For a fuller explanation, *see* Preamble, *infra*, at ___.

Section 27.32c. Partner services relating to HIV and AIDS.

IRRC commented that it understood the Department's reasoning in deleting a reference to the Confidentiality of HIV-Related Information Act, 35 P.S. §§ 7601-7612 ("Act 148"), from this section, and agreed with the Department's analysis that it was unnecessary. It requested, however, that the Department keep the language in the regulations as a clear notice to the regulated community. The Department agrees with the comment and has added the reference back into the section, but as a new subsection, Subsection (c).

Subsections (a) and (b) explain that a person providing testing services and giving diagnoses to an individual may ask the Department for help with counseling services. The regulation also makes it clear that the person providing those services must also tell the individual that the Department or a local health department representative may contact the person for a voluntary and confidential interview to discuss the services available to them. This is so the individual is kept informed and is not surprised by the potential contact from the Department. The reference to Act 148, pointing out the need to comply with the law relating to HIV confidentiality, fit more naturally following these subsections than at the beginning of the section. The Department has therefore added the reference in new Subsection (c).

Finally, the Department has also changed the word "patient," to "individual" and the phrase "who provides," to "providing" in order to make the construction of the subsections parallel.

D. COST AND PAPERWORK ESTIMATE

1. *Cost*

The amendments would have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public because the disease reporting system already exists in the Commonwealth. The financial and economic impact of the regulation outside of healthcare settings is very minimal. Healthcare practitioners, health care facilities and clinical laboratories currently are required to have systems in place to report some CD4 T-lymphocyte and HIV viral load test results into PA-NEDSS, so although the new regulation would result in reporting of all CD4 T-lymphocyte and HIV viral load results, they will not need to develop new systems. Currently, healthcare practitioners and clinical laboratories must separate out the CD4 T-lymphocyte and viral load test results required to be reported from those not required to be reported, and this process takes time and adds cost. The proposed change would allow reporters to report all the test results received and remove the need to separate the results into those reported and those not reported.

Healthcare practitioners and laboratories without the ability to send data electronically directly to the electronic disease surveillance system would be required to key enter these additional test results into that system. However, as noted earlier, most CD4 and HIV viral load information is received from hospital and commercial laboratories with IT systems allowing batch electronic reporting. For these facilities, once their IT system is modified to capture the additional test results, the data would automatically be extracted and submitted to the Department's system. There would therefore be no ongoing cost associated with the additional reporting requirements,

and the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

The costs to both the Commonwealth and to local governments would not increase because of these amendments. The Commonwealth, through the Department, and local health departments, already have infrastructure in place to accept reporting of diseases and conditions, and to carry out, as required by law, disease prevention and control activities relating to HIV and AIDS, among other things. The additional work and cost relating to the reporting of more cases would be minimal and is outweighed by the benefit accruing from better understanding of the epidemic that allows for more targeted intervention and prevention strategies. As noted above, in 2010, the cost per one HIV case in the Commonwealth over a life time was approximately $379,668.00. https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html. The cost savings of a case of HIV averted has been estimated at between $ 20,000 to $100,000 per case. *See* Woodak and Cooney, at 20-22; *see also WHO White Paper*, at 15-16. The Commonwealth saw 991 new cases of HIV in 2016. Pennsylvania Department of Health, Annual HIV Surveillance Summary (2016) http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/E-H/HIV%20And%20AIDS%20Epidemiology/Documents/Pennsylvania%202016%20Annual%20HIV%20Surveillance%20Report.pdf, accessed July 2, 2018. Using these figures, the cost to the Commonwealth of those 991 cases could be as high as $376,250,998.00. Preventing them from occurring could be a savings of as much as $99,100,000.

2. *Paperwork*

Because the electronic disease surveillance system that receives and stores reports of diseases and conditions is already in place in this Commonwealth, expanding the list to include mandatory reports of all test results for an existing disease or condition and additional testing relating to that disease or condition would create no measurable increase in paperwork. Healthcare practitioners, health care facilities and clinical laboratories currently are required to have systems in place to report some CD4 T-lymphocyte and HIV viral load test results into PA-NEDSS, so although the amendments to the regulation would result in reporting of all CD4 T-lymphocyte and HIV viral load results, existing reporters should not need to develop new systems.

The ongoing savings each year from more effective HIV disease control, prevention, and timely treatment of individuals infected with HIV which would be expected to occur from this expanded reporting are immeasurable. All Pennsylvanians would benefit from these proposed amendments as they will allow the Department to monitor the proportion of persons with HIV who are under care and the proportion adequately treated. Identifying populations or areas with substandard levels of treatment could lead to interventions such as assisting patients with linkage to care and treatment before those patients develop significant and expensive medical complications. Furthermore, when people living with HIV are in continuous medical care and have a suppressed viral load, the chances of those persons transmitting HIV to other people is tremendously reduced. These proposed amendments would help to protect Commonwealth citizens from exposure to HIV and subsequent hardship, disability, or death. In addition, it would enable the Commonwealth to comply with the CDC's recommendations for effective HIV disease surveillance, control and patient management.

E. STATUTORY AUTHORITY

The Department obtains its authority to promulgate regulations relating to reporting of communicable and noncommunicable diseases from several sources. Section 16(a) of the Disease Prevention and Control Law of 1955 (the act) (35 P.S. §521.16(a)) gives the Board the authority to issue rules and regulations on a variety of matters relating to communicable and non-communicable diseases, including the following: the diseases that are to be reported; the methods of reporting diseases; the contents of reports; the health authorities to whom diseases are to be reported; the control measures that are to be taken with respect to different diseases; the enforcement of control measures; the immunization and vaccination of persons and animals; the prevention and control of disease in public and private schools; the treatment of sexually transmitted diseases, including patient counseling; and any other matters the Board may deem advisable to address for the prevention and control of disease and for carrying out the provisions and purposes of the act. Section 16(b) of the act (35 P.S. §521.16(b)) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. § 51 *et seq.*) Section 2102(g) of the Administrative Code (71 P.S. § 532(g)) gives the Department this general authority. Section 2111(b) of the Administrative Code of 1949 (71 P.S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section

further provides that the regulations of the Board shall become the regulations of the Department. Section 2106(a) of the Code (71 P.S. §536(a)) provides the Department with additional authority to declare diseases to be communicable, and to establish regulations for the prevention and control of disease.

Section 2111(b) of the Code (71 P.S. §541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

In addition, Section 803 of the Health Care Facilities Act) (35 P.S. §448.803) provides the Department with the authority to promulgate regulations relating to the licensure of health care facilities, and allows the Department to require certain actions relating to disease control and prevention to occur within health care facilities.

F. EFFECTIVENESS/SUNSET DATES

The amendments will be effective on publication in the *Pennsylvania Bulletin*. The Department will continually review and monitor the effectiveness of these regulations.

G. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. §§ 745.1 – 745.15), the Department submitted a copy of a Notice of Proposed Rulemaking, published at 49 Pa.B. 2605 (May 25,

2019), to the Independent Regulatory Review Commission ("IRRC") and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In compliance with Section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received during the formal comment period, as well as other documentation.

In compliance with Section 5.1(a) of the Regulatory Review Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on August 12, 2020. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

In preparing this final-form regulation the Department has considered all comments received from IRRC, the Committees and the public.

This final-form regulation was deemed approved by the House Health and Human Services Committee and deemed approved by the Senate Public Health and Welfare Committee. IRRC met on _____, and approved the regulation in accordance with Section 5.1(e) of the Regulatory Review Act.

H. CONTACT PERSON

Questions regarding these regulations may be submitted to Dr. Sharon Watkins, Director, Bureau of Epidemiology, Department of Health, 625 Forster St., Harrisburg, PA 17108, Rm 933, Health and Welfare Building , Harrisburg, PA 17120, (717) -787-3350, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulation may do so by using the above number or address. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800-654-5984[TT]). Persons who require an alternative format of this document may contact Dr. Watkins so that necessary arrangements may be made.

I. FINDINGS

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202), and the regulations thereunder, 1 Pa. Code §§7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The adoption of regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statute.

J. ORDER

The Department, acting under the authorizing statute, orders that:

(1) The regulations of the Department at 28 Pa. Code Chapter 27 are amended by amending §§ 27.21a, 22, 23, and 32a-32e as set forth in Annex A.

(2) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of Health shall submit this Order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(4) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(5) This order shall take effect upon its publication in the *Pennsylvania Bulletin.*

Department of Health Regulation No. 10-209
Commentator List

Thomas A. Farley, MD, MPH
Health Commissioner
City of Philadelphia
1101 Market Street, Suite 1320
Philadelphia, PA 19107

Michael Hellman
Community Co-Chair
Pennsylvania HIV Planning Group
1604 Jancey Street
Pittsburgh, PA 15206

Steven Novis
Director, Government Relations (Northeast)
On behalf of: ViiV Healthcare
18 Cooks Farm Road
Montville, NJ 07045

Robert G. Shipp III, MSHSA, RN, NEA-BC
Vice President, Quality and Population Health
On behalf of: The Hospital +Healthsystem Association of Pennsylvania
30 North Third Street, Suite 600
Harrisburg, PA 17101

Annex A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

Subchapter B. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS

GENERAL

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

***ELECTRONIC DISEASE SURVEILLANCE SYSTEM* – ANY OF THE ELECTRONIC, WEB-BASED PLATFORMS THAT THE DEPARTMENT USES TO COLLECT AND MANAGE INFORMATION REPORTABLE UNDER § 27.2 (RELATING TO SPECIFIC REPORTABLE DISEASES, INFECTIONS AND CONDITIONS, AND PUBLIC HEALTH EMERGENCIES). FOR PURPOSES OF THIS CHAPTER, THE TERM INCLUDES AN ELECTRONIC LABORATORY REPORTING SYSTEM.**

***ELECTRONIC LABORATORY REPORTING SYSTEM* – THE ELECTRONIC PLATFORM THAT THE DEPARTMENT USES TO RECEIVE AND PROCESS INFORMATION ELECTRONICALLY GENERATED BY CLINICAL LABORATORIES TO FULFILL THEIR REPORTING RESPONSIBILITIES UNDER § 27.22 (RELATING TO REPORTING OF CASES BY CLINICAL LABORATORIES). INFORMATION SUBMITTED TO THE ELECTRONIC LABORATORY REPORTING SYSTEM WILL**

BE ROUTED TO THE DEPARTMENT'S ELECTRONIC DISEASE SURVEILLANCE SYSTEM WHEN APPROPRIATE.

* * * * *

§ 27.4. Reporting cases.

(a) Except ~~for reporting by a clinical laboratory, a case is to be reported to the LMRO serving the area in which a case is diagnosed or identified unless another provision of this chapter directs that a particular type of case is to be reported elsewhere. A clinical laboratory shall make reports to the appropriate office of the Department~~ **WHERE OTHERWISE NOTED IN THIS CHAPTER, A CASE SHALL BE REPORTED TO THE DEPARTMENT THROUGH THE APPROPRIATE ELECTRONIC DISEASE SURVEILLANCE SYSTEM.**

(b) ~~Upon the Department's implementation of its electronic disease surveillance system for certain types of case reports, persons who make those reports shall do so electronically using an application and reporting format provided by the Department. At least 6 months in advance of requiring a type of case report to be reported electronically, the Department will publish a notice in the *Pennsylvania Bulletin* announcing when electronic reporting is to begin~~**A REPORTER MAY MAKE A PRELIMINARY REPORT OF A CASE BY TELEPHONE. THE PRELIMINARY REPORT MUST BE FOLLOWED BY A FORMAL REPORT MADE THROUGH THE APPROPRIATE ELECTRONIC DISEASE SURVEILLANCE SYSTEM.**

(c)~~This section does not prohibit a reporter from making an initial report of a case to the Department or an LMRO by telephone. The reporter will be instructed on how to make a complete case report at the time of the telephone call.~~

~~(d) Department offices to which this chapter requires specified case reports to be filed are as follows:~~

~~(1) Cancer Registry, Division of Health Statistics, Bureau of Health Statistics and Research.~~

~~(2) Division of Infectious Disease Epidemiology, Bureau of Epidemiology.~~

~~(3) HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.~~

~~(4) Division of Newborn Screening and Genetics, Bureau of Family Health.~~

~~(e)~~ A case shall be reported using the appropriate case report format. **THE REQUESTED** information ~~solicited by the case report form~~ shall be provided by the reporter, irrespective of ~~whether the report is made by submitting the form directly in hard copy or by telecommunication or electronic submission~~. ~~An appropriate case report form or format may be procured from the office to which the type of case is reportable~~**THE MANNER IN WHICH THE REPORT IS SUBMITTED. ACCESS TO THE APPROPRIATE**

ELECTRONIC DISEASE SURVEILLANCE SYSTEM MAY BE OBTAINED FROM THE DEPARTMENT UPON REQUEST.

* * * * *

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

(a) Except as set forth in this section or as otherwise set forth in this chapter, a health care practitioner or health care facility is required to report a case of a disease, infection or condition in subsection (b) as specified in § 27.4 (relating to reporting cases), if the health care practitioner or health care facility treats or examines a person who is suffering from, or who the health care practitioner or health care facility suspects, because of symptoms or the appearance of the individual, of having a reportable disease, infection or condition:

(1) A health care practitioner or health care facility is not required to report a case if that health care practitioner or health care facility has reported the case previously.

* * * * *

(b) The following diseases, infections and conditions in humans are reportable by health care practitioners and health care facilities within the specified time periods and as otherwise required by this chapter:

* * * * *

(2) The following diseases, infections and conditions are reportable within 5 work days afterbeing identified by symptoms, appearance or diagnosis:

AIDS.

Amebiasis.

Brucellosis.

CD4 T-lymphocyte **[test result with a count of less than 200 cells/µL or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes (effective October 18, 2002)]** **counts and percentages**.

Campylobacteriosis.

* * * * *

HIV (Human Immunodeficiency Virus) **[(effective October 18, 2002)]**.

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

Hepatitis, viral, acute and chronic cases.

* * * * *

§ 27.22. Reporting of cases by clinical laboratories.

(a) A person who is in charge of a clinical laboratory in which a laboratory test of a specimen derived from a human body yields microscopical, cultural, immunological, serological, chemical, virologic, nucleic acid (DNA or RNA) or other evidence significant from a public health standpoint of the presence of a disease, infection or condition listed in subsection (b) shall promptly report the findings, no later than the next work day after the close of business on the day on which the test was completed, except as otherwise noted in this chapter.

(b) The diseases, infections and conditions to be reported include the following:

* * * * *

CD4 T-lymphocyte **[test result with a count of less than 200 cells/µL or less than 14% of total lymphocytes (effective October 18, 2002)]** **counts and percentages**.

* * * * *

Granuloma inguinale.

HIV (Human Immunodeficiency Virus) **[(effective October 18, 2002)]**.

HIV viral load results, including detectable and undetectable viral load results, and HIV **genotype test results.**

Haemophilus influenzae infections—invasive from sterile sites.

* * * * *

(d) Laboratory test results shall be reported by the person in charge of a laboratory ~~directlyto theDepartment's Bureau of Epidemiology throughsecure electronic mechanismsin a manner specified by the Department, except for the following:~~**THROUGH THEAPPROPRIATE ELECTRONIC DISEASE SURVEILLANCE SYSTEM.** Reports of CAH, galactosemia maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell disease~~;~~**AND**cancer, ~~CD4 T-lymphocyte test results with a count of less than 200 cells/µL or less than 14% of total lymphocytes, HIV (Human Immunodeficiency Virus),and lead poisoning~~ shall be made in the manner ~~and to the location~~ specifically designated in this subchapter. See §§ 27.30~~;~~**AND** 27.31~~,27.32and 27.34~~.

* * * * *

§ 27.23. Reporting of cases by persons other than health care practitioners, health care facilities, veterinarians or laboratories.

Except with respect to reporting cancer, AIDS, CD4 T-lymphocyte **[test result with a count of less than 200 cells/µL or less than 14% of total lymphocytes]** **counts and percentages**, HIV test results or perinatal exposure of a newborn to HIV, **HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results,** individuals in charge of the following types of group facilities identifying a disease, infection or condition listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities) by symptom, appearance or diagnosis shall make a report within the timeframes required in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities):

(1) Institutions maintaining dormitories and living rooms.

(2) Orphanages.

(3) Child care group settings.

§ 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and nondetectable viral load results and HIV genotype test results, and perinatal exposure of newborns to HIV.

(a) *Reporting by clinical laboratories.*

(1) A person in charge of a clinical laboratory shall report CD4 T-lymphocyte **[test results as defined in § 27.22(b) (relating to reporting of cases by clinical**

laboratories)] **counts and percentages** electronically to the **[HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology,]** **Department through ~~the Department's~~THE APPROPRIATE electronic disease surveillance system** within 5 **work** days of obtaining the test results.

(2) A person in charge of a clinical laboratory shall report positive test results of any test approved by the FDA to establish the presence of HIV, including a serologic, virologic, nucleic acid (DNA or RNA) or any other type of test the FDA approves to establish the presence of HIV. The report shall be made to the **[HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology,]** **~~Department through the Department's~~APPROPRIATE electronic disease surveillance system**within 5 **work** days of obtaining the test results.

(3) **A person in charge of a clinical laboratory shall report HIV viral load test results, including detectable and undetectable viral load results, and HIV genotyping results, to the Department through ~~the Department's~~THE APPROPRIATE electronic disease surveillance system, within 5 work days of obtaining the test results.**

[(3)] **(4)** The report shall include the following information:

(i) The individual's name and the address, city, county, and zip code of the individual's residence.

(ii) The patient identifying number assigned to the individual by the physician or at the facility requesting the laboratory test.

* * * * *

[(4)] **(5)** To enable the laboratory to complete the report it is required to file with the Department, a person or entity that requests a laboratory test for HIV **[or],** a CD4 T-lymphocyte count **or percentage, or HIV viral load test results, including detectable or nondetectable test results, and** HIV **genotype test results** shall provide to the laboratory the information in subsection **[(a)(3)]** **(a)(4)**, with the exception of subparagraphs (vi)—(ix). In addition to the information included in subsection **[(a)(3)]** **(a)(4)**, a person or entity that requests a laboratory test for HIV **[or],** a CD4 T-lymphocyte count **or percentage, an HIV viral load test result, including detectable or nondetectable test results, and** HIV **genotype test results** shall provide to the laboratory the date each test was requested and the type of test or tests requested.

(b) *Reporting by* ***[physicians]*** ***health care practitioners****, hospitals,* ***and other****persons or entities, who diagnose AIDS or who receive or provide HIV* ***[and]*** ***test results,*** *CD4 T-lymphocyte* ***[test results]*** **counts and percentages, or HIV viral load test results, including detectable and nondetectable results, and** HIV **genotype test results**.

(1) A **[physician]** **health care practitioner**, hospital, person providing HIV services or person in charge of an entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV **[or]** **test results,** CD4 T-lymphocyte **[test results]** **counts and percentages, HIV viral load test results, including detectable and nondetectable results, or** HIV **genotype test results,** or **who** provides **an AIDS diagnosis,** HIV **[or]** **test results,** CD4 T-lymphocyte **[test results]** **counts and percentages, HIV viral load test results, including detectable and nondetectable test results, and HIV genotype test results** to patients, shall report the following to the **[LMRO responsible for the geographic area in which the person is tested or diagnosed]** **Department through**

the ~~Department's~~APPROPRIATE electronic disease surveillance system within 5 **[business] work** days of the diagnosis of AIDS or the receipt of the results of the test:

(i) A diagnosis of AIDS.

(ii) A positive result of any test approved by the FDA to establish the presence of HIV, including a serologic, virologic, nucleic acid (DNA or RNA) or any other type of test the FDA approves to establish the presence of HIV **[(effective October 18, 2002)]**.

(iii) **[A]** CD4 T-lymphocyte **[test result with a count of less than 200 cells/µL or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes (effective October 18, 2002)] counts and percentages**.

(iv) A perinatal exposure of a newborn to HIV **[(effective October 18, 2002)]**.

(v) HIV viral load results, including detectable and undetectable viral load results, and HIV genotype test results.

(2) A report of an HIV test result, CD4 T-lymphocyte count **and percentage, HIV viral load test result, including detectable and nondetectable test results, and HIV genotype test result,** AIDS case based on the CDC case definition, or perinatal exposure of a newborn to HIV shall include the following information:

* * * * *

(xi) The name, address and telephone number of the **[physician] health care practitioner**, hospital, or other person or entity that secured a specimen from the individual and submitted it for laboratory testing.

(xii) The name, address and telephone number of the entity in which the **AIDS** diagnosis was made or that received the HIV test result **[or],** CD4 T-lymphocyte count **and percentage, HIV viral load test results, including detectable and nondetectable test results, or** HIV **genotype test results.**

* * * * *

(4) **[An LMRO] A local health department** receiving reports of diagnoses of AIDS, positive HIV test results, **[reportable]** CD4 T-lymphocyte counts **and percentages, HIV viral load test results, including detectable and nondetectable test results, and** HIV **genotype test results**, and perinatal exposures to HIV shall forward completed case reports containing the information included in paragraph (2) **[electronically]** to the **[Department's Bureau of Epidemiology through a secure electronic medium specified by the]** Department **through the Department's electronic disease surveillance system**.

§ 27.32b. Confidential and anonymous testing.

* * * * *

(b) Anonymous test results shall be reported in accordance with § 27.32a(b)(2) (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts **and percentages, HIV viral load test results, including detectable and nondetectable test results, and** HIV **genotype test results** and perinatal exposure of newborns to HIV). In lieu of the information required in § 27.32a(b)(2)(i), the report of an anonymous test shall include an assigned number preprinted on the HIV counseling and testing report form. The report shall also include the individual's county of residence.

* * * * *

§ 27.32c. [Counseling, testing, referral and partner notification services] Partner services relating to HIV and AIDS.

[Counseling, testing referral and partner notification services shall be performed in accordance with the Confidentiality of HIV-Related Information Act (35 P.S. §§ 7601—7612).]

(a) A person providing **an AIDS diagnosis,** HIV test results**, CD4 T-lymphocyte counts and percentages, HIV viral load test results including detectable and nondetectable viral load test results, or HIV genotype test results** to ~~a patient~~**AN INDIVIDUAL**may ask for the Department's assistance with counseling if the person chooses to do so.

(b) A person ~~who provides~~PROVIDING an AIDS diagnosis, HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and nondetectable viral load test results, or HIV genotype test results to an individual shall inform the individual that the Department or a local health department may contact the ~~patient~~INDIVIDUAL for a voluntary confidential interview to discuss partner services, including counseling, testing, referral and partner notification.

(C) COUNSELING, TESTING REFERRAL AND PARTNER NOTIFICATION SERVICES SHALL BE PERFORMED IN ACCORDANCE WITH THE CONFIDENTIALITY OF HIV-RELATED INFORMATION ACT (35 P.S. §§ 7601—7612).

§ 27.32d. Department authority to require complete reporting.

The Department will have access to and may review the patient records of **[physicians]** **health care practitioners**, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of AIDS, or who receive or provide HIV **[and]** **test results,** CD4 T-lymphocyte **[test results]** **counts or percentages, HIV viral load test results including detectable and nondetectable test results, or** HIV **genotype test results**. Access and review will enable the Department to conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays and to investigate other reporting problems.

§ 27.32e. Record audits.

(a) The Department may conduct record audits of the records of **[physicians]** **health care practitioners**, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of AIDS or who receive or provide HIV test results, **CD4 T-lymphocyte counts and percentages, HIV viral load test results including detectable and nondetectable test results, or** HIV **genotype test results** for the purpose of obtaining information allowing the Department to complete HIV **[and]**, CD4 T-lymphocyte case reports, **and viral load and** HIV **genotyping case reports** to aid it in tracking trends in disease and obtaining additional funding for prevention and treatment programs. The Department may audit records going back to January 1, 2000, for this purpose.

(b) The Department may require special reports of persons or entities required to report under this chapter to ensure compliance with this chapter.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH

August 12, 2020

David Sumner
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health – Final Regulation No. 10-209
Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV Regulations
28 Pa. Code §§ 27.1, 27.4, 27.21a, 27.22, 27.23, and 27.32a-32e

Dear Mr. Sumner:

Enclosed is a copy of the above-referenced final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). These final-form regulations amend 28 Pa. Code §§ 27.1, 27.4, 27.21a, 27.22, 27.23 and 27.32a-32e, to require reporting of all CD4 T-lymphocyte cell counts and percentages related to HIV infection, as well as all viral load test results, including detectable and undetectable viral loads, and genotyping test results related to HIV.

The Act provides that, upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the Standing Committees, a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt. *See* 71 P.S. §§745.5a(a).

The Department received four comments to the proposed rulemaking. A list of the names and addresses of the commentators who requested a copy of the final- form regulations is enclosed. These comments were forwarded to the Commission upon receipt by the Department.

The Act also provides that IRRC may have until its next scheduled meeting which occurs no less than 30 days after receipt of the final-form regulation to approve or disapprove the final-form regulation. 71 P.S § 745.5a(e).

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact David Toth, Director, Office of Legislative Affairs, at (717) 787-7262.

Sincerely,

Rachel L. Levine, M.D.
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-209
SUBJECT:	Complete Reporting of CD4 T- Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV
AGENCY:	DEPARTMENT OF HEALTH

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON HEALTH
8-12-20		MAJORITY CHAIR Kathy L. Rapp
8/12/20		MINORITY CHAIR Dan Frankel
		SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES
		MAJORITY CHAIR
		MINORITY CHAIR
		INDEPENDENT REGULATORY REVIEW COMMISSION
		~~*ATTORNEY GENERAL*~~ (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

From:	Bulletin
To:	mbrooks@pasen.gov; senatorhaywood@pasen.gov; rdellinger@pasen.gov; clarissa.freeman@pasenate.com
Cc:	A.J. Mendelsohn; Vincent Deliberato; Duane Searle; Martin, Megan; Smith, Pamela (LI-OCC)
Subject:	[External] Delivery of Final Rulemaking—Department of Health, Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV Regulations, 10-209
Date:	Wednesday, August 12, 2020 12:37:10 PM
Attachments:	Brooks_10-209_Final.pdf Haywood_10-209_Final.pdf

We have attached Final Rulemaking No. 10-209 from the Department of Health.

Please confirm receipt of this email by replying to all.

Thank you.

The Pennsylvania Code & Bulletin Office

From:	Brooks, Senator Michele
To:	bulletin@palrb.us; Dellinger, Ryan; Smith, Pamela (LI-OCC)
Subject:	RE: Delivery of Final Rulemaking—Department of Health, Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV Regulations, 10-209
Date:	Wednesday, August 12, 2020 6:07:33 PM

Thank you! We have received this notice and will share with the Committee

Best, Michele

From: Brooks, Senator Michele <mbrooks@pasen.gov>
Sent: Wednesday, August 12, 2020 12:49 PM
To: McNaughton, Diane <dmmcnaughton@pasen.gov>; Dellinger, Ryan <rdellinger@pasen.gov>
Subject: FW: Delivery of Final Rulemaking—Department of Health, Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV Regulations, 10-209

From DH

From: Bulletin <bulletin@palrb.us>
Sent: Wednesday, August 12, 2020 12:34 PM
To: Brooks, Senator Michele <mbrooks@pasen.gov>; senatorhaywood@pasen.gov; Dellinger, Ryan <rdellinger@pasen.gov>; clarissa.freeman@pasenate.com
Cc: A.J. Mendelsohn <amendelsohn@palrb.us>; DeLiberato, Vincent C. (LRB) <vdeliberato@palrb.us>; Duane Searle <dsearle@palrb.us>; Martin, Megan (OS) <mtmartin@os.pasen.gov>; Smith, Pamela (LI-OCC) <pamesmith@pa.gov>
Subject: Delivery of Final Rulemaking—Department of Health, Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV Regulations, 10-209

We have attached Final Rulemaking No. 10-209 from the Department of Health.

Please confirm receipt of this email by replying to all.

Thank you.

The Pennsylvania Code & Bulletin Office

From: Freeman, Clarissa
To: Smith, Pamela (LI-OCC); Bulletin@palrb.us
Cc: Haywood, Senator Art; Lewis, Dwight
Subject: Re: Delivery of regulation
Date: Wednesday, August 12, 2020 11:03:47 AM

Received by Clarissa Freeman
Thank you,
Clarissa
Get Outlook for iOS

From: Smith, Pamela (LI-OCC) <pamesmith@pa.gov>
Sent: Wednesday, August 12, 2020 10:59:41 AM
To: Bulletin@palrb.us <Bulletin@palrb.us>
Cc: rdellinger@pasen.gov <rdellinger@pasen.gov>; Freeman, Clarissa <Clarissa.Freeman@pasenate.com>
Subject: Delivery of regulation

■ EXTERNAL EMAIL ■

Good morning:

Pursuant to SR 318, authorizing the Legislative Reference Bureau to transmit regulations to the appropriate committees for consideration, we are submitting Final Rulemaking 10-209, Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV, to the Senate Health and Human Services Committee.

Please provide written (email) confirmation that this rulemaking was received by each of the offices of the respective Committee chairs.

Sincerely,

Pamela G. Smith | Assistant Counsel
Pennsylvania Department of Health | Office of Legal Counsel
625 Forster Street, Room 825 | Harrisburg, PA 17120
Phone: 717.783.2500 | Fax: 717.705.6042
www.health.state.pa.us