Regulatory Analysis Form

(Completed by Promulgating Agency)

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INDEPENDENT REGULATORY REVIEW COMMISSION

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(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 all viral load test results and genotyping results.

The spread of HIV is a serious public health issue. By the end of 2016, 35,483 individuals were diagnosed and living with HIV infection in Pennsylvania. 6,168 new HIV cases were diagnosed in the last five years (2012 to the end of 2016), accounting for 17.4% of all of those diagnosed and living with HIV infection by 2016. The estimated number of people living with HIV has increased each year on average by approximately 1,325 persons. With a growth curve following a very strong linear trend, projections indicate that, by 2020, there could be as many as 42,000 people in Pennsylvania living with HIV.
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 act. Section 16(a) of the Disease Prevention and Control Law of 1955 ("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.

(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. 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 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, at the time of the letter, 6 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 hereto as Exhibit "B". Since that letter was written, 2 more states have required all CD4 t-lymphocyte test results to be reported. Pennsylvania is now one of only 4 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 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.

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 2016, 35,483 individuals were diagnosed and living with HIV infection in this Commonwealth. 6,168 new HIV cases were diagnosed in the last five years (2012 to the end of 2016), accounting for 17.4% of all of those diagnosed and living with HIV infection by 2016. The estimated number of persons living with HIV has increased each year on average by approximately 1,325 persons. With a growth curve following a very strong linear trend, projections indicate that, by 2020, there could be as many as 42,000 people in this Commonwealth living with HIV.

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 "E."*

(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, bas 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 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* 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 "E."

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

These proposed amendments would not affect the regulations of any other state agency. The Department is currently revising other parts of the regulations relating to communicable and noncommunicable diseases (28 Pa. Code Ch. 27), but this proposed amendment would 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 also provides requested updates to the Statewide HIV Planning Group (HPG). 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 is in support of CD4 and viral load reporting. *See Letter from HIV Planning Group*, dated December 21, 2016 (attached hereto as *Exhibit "D"*).

(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 are required to comply with the existing regulations relating to the reporting of AIDS and HIV disease, including specified CD4 T-lymphocyte test results. These same types of providers, facilities and laboratories would be required to comply with these proposed 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. Therefore, the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

All persons affected by or infected with HIV/AIDS would be impacted by these amendments. All Pennsylvanians would benefit from this proposed amendment 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. This proposed amendment 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 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 are required to comply with the existing regulations relating to the reporting of AIDS and HIV disease, including specified CD4 T-lymphocyte test results. These same providers, facilities and laboratories would be required to comply with these proposed amendments to the disease reporting requirements

relating to HIV. The proposed 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) would be required to comply with the proposed 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).

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

The financial and economic impact of the proposed amendments outside of healthcare settings would be very 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 based on regulation and this process takes time and adds cost. The proposed change would allow them to report all the test results and remove the need to separate the results before reporting. 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. 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. Therefore, the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

Moreover, the ongoing savings each year from more effective HIV disease control, prevention, and timely treatment of individuals infected with HIV would be immeasurable. All Pennsylvanians would benefit from this proposed amendment 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. This proposed amendment 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 CDC recommendations for effective HIV disease surveillance, control and patient management.

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 2016, 35,483 individuals were diagnosed and living with HIV infection in this Commonwealth. 6,168 new HIV cases were diagnosed in the last five years (2012 to the end of 2016), accounting for 17.4% of all of those diagnosed and living with HIV infection by 2016. The estimated number of persons living with HIV has increased each year on average by approximately 1,325 persons. With a growth curve following a very strong linear trend, projections indicate that, by 2020, there could be as many as 42,000 people in this Commonwealth living with HIV.

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 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* 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 "E."*

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

The economic costs of this proposed amendment are minimal. The costs associated with additional reporting of CD4 and HIV viral load tests and reporting of genotyping tests would be 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* 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 "E."*

(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 financial and economic impact of the proposed amendments outside of healthcare settings would be very minimal. Health care practitioners, health care facilities,clinical laboratories and other persons or entities who diagnose AIDS or who receive or provide HIV test results and CD4 T-lymphocyte test results are already 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 based on regulation and this process takes time and adds cost. The proposed change would allow them to report all the test results and remove the need to separate the results before reporting. 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. 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. Therefore, the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

(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 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.

(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.

Health care practitioners, health care facilities, clinical laboratories and other persons or entities who diagnose AIDS or who receive or provide HIV test results and CD4 T-lymphocyte test results are already required to have systems in place to report some CD4 and HIV viral load test results into PA-NEDSS, and also have whatever legal, accounting or consulting procedures are necessary to accomplish these requirements. 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 or processes. Currently, health care practitioners and clinical laboratories have to separate CD4 and viral load test results based on regulation and this process takes time and adds cost. The proposed change would allow them to report all the test results and remove the need to separate the results before reporting. 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. 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. Therefore, the cost of the additional reports required as a result of the proposed changes to the regulation would be negligible.

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

No. The proposed amendments require reporting through an existing electronic disease surveillance system that has been in place in the Commonwealth since 2002. Reporters without access to PA-NEDSS are able to send the report by mail.

(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/ Reporters without access to PA-NEDSS would still be able to send the report by mail; the number of reporters not using PA-NEDSS to report to the Department is very small. No additional forms are required for implementation of the program.

(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

[1] Because the amendment would 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

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
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	$17,436,000	$12,436,000

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 gotten 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 virtually 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 2009, the cost per one HIV case in the Commonwealth over a life time was approximately $366,935. 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, however, minimal, and the cost to that regulated community should also be minimal. Should reporters choose to update their systems to respond to these regulations, the ultimate cost should go down, and ease of reporting should rise.

[5] See Footnote 2, supra.

[6] See Footnote 2, supra.

(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.

(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 proposed amendments are 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 proposed amendments is the prevention and control of the spread of disease. Compliance, including reporting, from all regulated communities, with these proposed amendments

would be 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 to report recognized communicable diseases and that requirement would continue under these proposed regulations. Any increase in reporting responsibilities as a result of proposed changes 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. Moreover, these reports could be made electronically or by telephone call to a local health department as needed. 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 has proposed 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 proposed amendments to the communicable disease regulations that would impose an added burden to the small business community beyond that which already exists based on the Department's current regulation. The Department is proposing to expand 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

propose to change the existing time frames for reporting CD4 T-lymphocyte test results and other HIV test results. Current regulations require reporting of these results within 5 days of receipt of the test result; the proposed amendments, while requiring reporting of all tests, would not change the time frames for reporting. Five days is the longest time period in the Department's existing 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. For this reason, the Department has not proposed to consolidate reporting requirements. The proposed amendments would, however, simplify reporting, since required reporters would 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 PA-NEDSS, would not change, nor would 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 4 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 will accept public comment for 30 days after publication of the proposed rulemaking in the *Pennsylvania Bulletin* on _____.

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.

C. The Department expects to publish Final Rulemaking in the *Pennsylvania Bulletin* on or before December of 2019.

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

"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

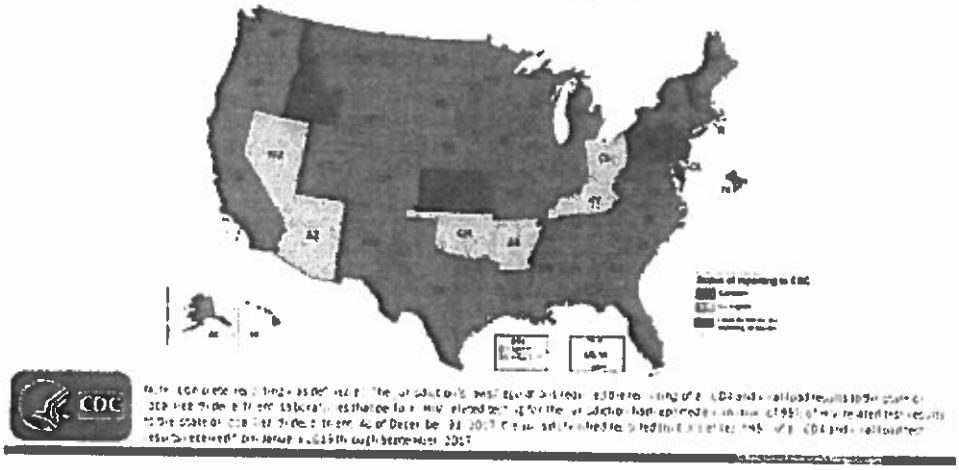
From: Peruski, Anne (CDC/OID/NCHHSTP)
Sent: Monday, July 9, 2018 10:56 AM
To: Satcher Johnson, Anna (CDC/OID/NCHHSTP) ; Selik, Richard (CDC/OID/NCHHSTP)
Subject: RE: states without complete cd4 reporting

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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EXHIBIT "E"

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

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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

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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 ≥200 cells/μL or ≥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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	BY Rachel L. Levine, M.D.	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
Check if applicable. Copy not approved. Objections attached.	TITLE Secretary of Health	Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

SUBCHAPTER A. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS

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

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

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

A. PURPOSE OF THE PROPOSED AMENDMENTS

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 require the reporting of all CD4 T-lymphocyte cell counts and percentages relating to HIV infection, as well as all viral load test results, including detectable and undetectable viral loads, and genotyping results.

The spread of HIV is a serious public health issue. By the end of 2016, 35,483 individuals were diagnosed and living with HIV infection in Pennsylvania. 6,168 new HIV cases were diagnosed in the last five years (2012 to the end of 2016), accounting for 17.4% of all of those diagnosed and living with HIV infection by 2016. The estimated number of people living with HIV has increased each year on average by approximately 1,325 persons. With a growth curve following a very strong linear trend, projections indicate that, by 2020, there could be as many as 42,000 people in Pennsylvania living with HIV.

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 federal Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (HHS) 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 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*

[1] At the time the letter was sent, the Commonwealth was one of 6 states that did not collect all CD4 test results. That number has since fallen to 4. See Preamble at 3.

and Prevention, and Jonathan A. Mermin, M.D., M.P.H, RADM and 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 4 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".

Persons tested for HIV have recorded CD4 and viral load test results, 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 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 would be more able to ensure that those identified as 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 "E."

At the present time, Pennsylvania is 1 of only 4 states in the nation that do not require the reporting of all CD4 test results and 1 of only 2 states that do not require the reporting of all viral load 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. 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. *See* Exhibit "B".

Although the recommendations are directed mainly towards complete laboratory reporting, the Department's proposed amendments would not merely revise the existing laboratory reporting section. The Department is proposing to make the same changes to reporting by health care practitioners and facilities and other persons or entities who diagnose AIDS or who receive or provide CD4 or HIV viral load test results. Those persons are currently required to report some of these test results, as are laboratories. In the interest of complete reporting, the Department is proposing to require complete

reporting of these particular providers, as well as of laboratories. As the National HIV/AIDS Strategy notes:

> HIV surveillance data are used extensively to target and evaluate HIV prevention and care programs. Therefore, comprehensive and timely data are critical, as are continued improvements in electronic laboratory reporting as timely receipt of laboratory data is critical. 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 (emphasis added). Reporting from all available sources is the best avenue to obtain all required information, and to work towards the vision that "The United States will become a place where new HIV infections are rare, and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination." *National HIV/AIDS Strategy*, VISION.

B. REQUIREMENTS OF THE PROPOSED AMENDMENTS

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES
SUBCHAPTER A. GENERAL PROVISIONS

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

This section requires health care practitioners and health care facilities to report the listed diseases, infections and conditions to the Department within a specified time frame. The Department is proposing to amend this section to require the reporting of all CD4 T-lymphocyte test results, not just results at or below a certain count or percentage. This would include counts and percentages of T-lymphocyte cells of all tests. In addition, the

Department is proposing to require the reporting of all HIV viral load test results, even those that are undetectable, and all HIV genotype test results.

The availability of highly effective retroviral therapy makes it much more important to monitor all test results, including CD4 T-lymphocyte counts in individual patients, viral loads and HIV genotype test results, and to use that information to track population health improvements and quality of care among persons infected with HIV. Obtaining data on all test results would help to identify HIV cases, identify when persons with HIV infection enter treatment, determine the stage of disease, measure unmet health care needs among HIV infected persons, and evaluate HIV testing and screening activities. With this information, the Department should be able to offer to practitioners and their patients more effective tools to combat each individual's infection and would be itself better prepared to assign resources and recommend strategies for combatting the epidemic.

Section 27.22. Reporting of cases by clinical laboratories.

This section requires reporting of test results by clinical laboratories. The Department is proposing to amend this section to require the reporting of all CD4 T-lymphocyte counts and percentages, not just results at or below a certain count or percentage. In addition, the Department is proposing the reporting of all HIV viral load test results and all HIV genotype test results. The Department believes that this addition is necessary to track the

spread of the disease across the Commonwealth and to more effectively target prevention and intervention efforts.

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

This section requires the reporting of cases of reportable diseases and conditions by persons other than health care practitioners, health care providers and laboratories. The Department has made revisions to this section to reflect the additions and revisions to sections 27.21a and 27.22, *supra*.

§ 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.

This section currently requires reporting of AIDS, CD4 T-lymphocyte counts and percentages below a certain amount and perinatal exposure of newborns to HIV by both physicians and laboratories. The Department proposes to amend the title, and the remainder of the section, to reflect the proposed reporting of all CD4 T-lymphocyte counts and percentages, all viral load results and all genotype test results, as well as the required reporting of the other listed tests.

In subsection (a), relating to reporting by clinical laboratories, the Department has maintained the time frame for reporting for CD4 T-lymphocyte counts and percentages at

5 days, and has clarified that these would be work days, and not calendar days. The Department has proposed adding a time frame for viral load test results and HIV genotype test results, which would also be reportable within 5 days of the reporting entity obtaining those test results. *See* new Subsection (a)(3). The Department also proposed revisions acknowledging that the Department's electronic disease surveillance system (NEDSS) is operational; it was not at the time the current regulations were promulgated. *See* proposed revisions to subsection (a)(1) and (2).

The Department has proposed the same revisions regarding time frames and its NEDSS system to revised subsection (b), relating to reporting by health care practitioners, hospitals, and other persons or entities, who diagnose AIDS or who receive or provide HIV test results, CD4 T-lymphocyte counts and percentages, or HIV viral load test results and HIV genotype test results. The Department also proposes to revise subsection (b) to clarify that clinicians, other than physicians, are required to report cases of AIDS, HIV, CD4 T-lymphocyte counts and percentages pertaining to HIV infection, HIV viral load test results and HIV genotype testing and perinatal exposure of newborns to HIV. The Department has, therefore, replaced the term, "physician," with the more general term, "health care practitioner."

Finally, the Department has proposed eliminating the term, "LMRO," or "Local Morbidity Reporting Office," from the regulation. At the time HIV reporting was added to the Department's regulations relating to communicable and noncommunicable diseases, electronic reporting had not yet been introduced. Reporting was done on paper

or by telephone and through the Department's 6 regional offices and 10 county/municipal health departments, known as its local morbidity reporting offices, or LMROs. Now that electronic reporting has become the norm, there is no need for this type of reporting structure. The Department, therefore, is proposing to replace the term, "LMRO," with the term previously in use, "local health department." *See* proposed revisions to subsection (b)(4).

§ 27.32b. Confidential and anonymous testing.

This section details the requirements for anonymous testing sites within the Commonwealth. The Department is proposing to amend the section to reflect the proposed additions and revisions to sections 27.21a and 27.22, *supra*.

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

This section would be significantly revised. The Department is proposing to revise this section to reflect proposed amendments to sections 27.21a and 27.22 of these regulations, and changes to terminology relating to public health services offered to a patient being provided with an AIDS diagnosis, HIV test result, CD4 T-lymphocyte count or percentage, HIV viral load test result, including detectable and nondetectable viral load test results, or genotype test result. The regulations do not require a reference to the Confidentiality of HIV-Related Information Act (35 P.S. §§ 7601-7612), *as amended*, in order for the requirements of that Act to be in place and followed. The Department has, however, added proposed subsection (b) to make it clear that a person providing that information must also inform his or her client that the Department or a local health

department might be contacting the client to discuss the availability of partner services beneficial to that client and the client's partners.

Section 27.32d. Department authority to require complete reporting.

This section is not new; however, the Department is proposing to change the language to comport with revisions proposed to sections 27.21a, 27.22 and 27.32a.

Section 27.32e. Record audits.

This section is not new; however, the Department is proposing to change the language to comport with revisions proposed to sections 27.21a, 27.22 and 27.32a.

C. AFFECTED PERSONS

The proposed amendments, which add reporting requirements, would impact all health care practitioners, health care facilities and other persons or entities providing HIV services who diagnose AIDS or who provide or receive HIV, CD4 T-lymphocyte counts or percentages, viral load test results or HIV genotype test results. They are required to report to the Department diagnosed cases of AIDS, HIV test results, all CD4 T-lymphocyte counts and percentages, all viral loads, both detectable and undetectable, and all HIV genotype test results. The proposed amendments would also affect laboratories, which are required to report to the Department HIV test results, all CD4 T-lymphocyte counts and percentages, all viral loads, both detectable and undetectable, and all HIV genotype test results.

The proposed amendments would also affect the 10 county/municipal health departments that are involved in the reporting system.

The proposed regulations would also impact all persons who have been given an HIV, CD4, viral load or HIV genotyping test. The required reporting of these test results permits the Department to obtain more accurate information regarding the trends of the disease, and, therefore, to better target funding to programs that would provide maximum benefit to these individuals. Obtaining data on all test results would help to identify HIV cases, identify when persons with HIV infection enter treatment, determine the stage of disease, measure unmet health care needs among HIV infected persons, and evaluate HIV testing and screening activities.

The Department provides requested updates to the Statewide HIV Planning Group (HPG). 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 is in support of CD4

and viral load reporting. *See Letter from HIV Planning Group*, dated December 21, 2016 (attached hereto as Exhibit "D").

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 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. For these facilities, once their IT system is modified to capture the additional test results, the data would automatically be extracted and uploaded to PA-NEDSS. 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.

2. *Paperwork*

Because the electronic disease surveillance system (PA-NEDSS) 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. Reporters without access to PA-NEDSS would still be able to send the report by mail; the number of reporters not using PA-NEDSS to report to the Department is very small.

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 through the improved tracking of trends in HIV infection and treatment success, as well as assisting patients with linkage to care and treatment before those patients develop significant and expensive medical complications. 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's overarching authority to promulgate these regulations is found in the act. 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 regulations will become effective upon final publication in the Pennsylvania Bulletin. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

G. REGULATORY REVIEW

Under section 5(a) of the Regulatory Review Act, the act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§ 745.1-745.15), the Department submitted a copy of these proposed regulations on MAY 15 2019, 20__, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Health Committee and the Senate Health and Human Services Committee. In addition to submitting the proposed regulations, the

Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed regulations within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria that have not been met. The act specifies detailed procedures for review, prior to final publication of the regulation, by the Department, the General Assembly and the Governor of comments, recommendation or objections raised.

H. CONTACT PERSON

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Sharon Watkins, Ph.D., Director, Bureau of Epidemiology, Department of Health, 625 Forster Street, 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 regulations may do so by using V/TT (717) 783-6514 for speech and/or hearing-impaired persons 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.

ANNEX A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASE

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASE

SUBCHAPTER B. REPORTING OF COMMUNICABLE AND NONCOMMUNICABLE DISEASES

GENERAL

§ 27.21. Reserved.

§ 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 after being 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)

HIV viral load test results, including detectable and undetectable viral load results, and all 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)]**<u>**counts and percentages.**</u>

* * *

Granuloma inguinale.

<u>**HIV viral load results, including detectable and undetectable viral load results, and genotype test results.**</u>

Haemophilus influenzae infections – invasive from sterile sites.

* * *

§ 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]** <u>**counts and percentages**</u>, HIV

test results or perinatal exposure of a newborn to HIV, **HIV viral load results, including detectable and undetectable viral load results, and 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 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 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 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 genotyping results, to the Department through the Department's electronic disease surveillance system, within 5 work days of obtaining the test results.**

(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.

* * *

(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 genotype test results** shall

provide to the laboratory the information in subsection (a)**[(3)]**__(4)__, with the exception of subparagraphs (vi)—(ix). In addition to the information included in subsection (a)**[(3)]**__(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 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* ***test results, [and]*** *CD4 T-lymphocyte* **[***test results***]** __***counts and percentages, or HIV viral load test results, including detectable and nondetectable results, and 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 __**test results,[or]**__ CD4 T-lymphocyte**[** **test results]** __**counts and percentages, HIV viral load test results, including detectable and nondetectable results, or genotype test results,**__ or __**who**__ provides __**an AIDS diagnosis,**__ HIV __**test results,[or]**__ CD4 T-lymphocyte**[** **test results]** __**counts and percentages, HIV viral load test results, including detectable and nondetectable test results, and 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**__

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 genotype test results.

(2) A report of an HIV test result, CD4 T-lymphocyte **count and percentage,[** or**]** **HIV viral load test result, including detectable and nondetectable test results, and 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 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 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 genotype test results** and perinatal exposure of newborns to HIV. * * *

§ 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 genotype test results** to a patient may ask for the Department's assistance with counseling if the person chooses to do so.

(b) **A person who provides 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 genotype test results to an individual shall inform the individual that the Department or a local health department may contact the patient for a voluntary confidential interview to discuss partner services, including counseling, testing, referral and partner notification.**

§ 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 receive or provide HIV **test results, [and]**CD4 T-lymphocyte**[test results]counts or percentages, HIV viral load test results including detectable and nondetectable test results, or 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 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 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

MAY 15 2019

RECEIVED
IRRC
2019 MAY 15 P 3:36

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

Re: Department of Health – Proposed Regulation No. 10-209
Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV Regulations

Dear Mr. Sumner:

Enclosed are proposed regulations for review by the Independent Regulatory Review Commission (Commission) in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). The proposed regulations would require the reporting of all CD4 T-lymphocyte cell counts and percentages relating to HIV infection, as well as all viral load test results, including detectable and undetectable viral loads, and genotyping test results. Current reporting requirements call for the reporting of CD4 T-lymphocyte test results with a count of less than 200 cells/uL or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes. Ultimately, requiring the reporting of all CD4 T-lymphocyte and viral load test results and genotyping would allow the Department of Health 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.

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on May 25, 2019. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act, 71 P.S. § 745.5a(a), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received, the names and addresses of the 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.

The Department will provide the Commission within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations.

If you have any questions, please contact Erin Molchany, Director of the Office of Legislative Affairs, at (717) 787-6436.

Sincerely,

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

Enclosures

I.RRC

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

RECEIVED
IRRC
2019 MAY 15 P 3:37

TYPE OF REGULATION

X Proposed Regulation

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
5-15-19	Lori A. Ouellette	*HOUSE COMMITTEE ON HEALTH* MAJORITY CHAIR Kathy L. Rapp
5/15/19	Tracy Rock	MINORITY CHAIR Dan Frankel
5/15/19	Michele Adams	*SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES* MAJORITY CHAIR Michelle Brooks
5/15	[illegible]	MINORITY CHAIR Art Haywood
5/15/19	Cheryl Yourshaw	*INDEPENDENT REGULATORY REVIEW COMMISSION*
		~~*ATTORNEY GENERAL* (for Final Omitted only)~~
5/15/19	Connie Kratt	*LEGISLATIVE REFERENCE BUREAU* (for Proposed only)

April 25, 2019