Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	RECEIVED 2001 APR 10 PM 3:27 REVIEW COMMISSION IRRC Number: 2185
(2) I.D. Number (Governor's Office Use) 10-166	

(3) Short Title
Communicable and Non-Communicable Diseases

(4) Pa Code Cite	(5) Agency Contacts & Telephone Numbers
28 Pa. Code Ch. 27	Primary Contact: Joel H. Hersh, M.Ed., M.P.A. Director, Bureau of Epidemiology (717) 783-4677 Secondary Contact: Benjamin R. H. Muthambi, MPH, DrPH (717) 783-0481

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
_x_ Proposed Rulemaking	_x_ No
Final Order Adopting Regulation	Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The Department is proposing regulations which would require name reporting of individuals (1) who have had positive test results from any test approved by the Food and Drug Administration (FDA) to establish the presence of the Human Immunodeficiency Virus (HIV), including serologic, virologic, nucleic acid (DNA or RNA), or other tests that the FDA approves to establish the presence of HIV, (2) whose CD4 T-lymphocyte cell counts are below 200 cells per 1/1000 of a liter of blood or whose CD4 T-lymphocyte percentage of all lymphocytes falls below 14% and (3) who are women whose newborns have been perinatally exposed to HIV. The proposed regulations would also clarify that AIDS is reportable based on the Centers for Disease Control and Prevention's (CDC) case definition. This definition includes presumptive diagnoses of AIDS based on AIDS defining illnesses plus laboratory confirmation of HIV infection.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department obtains its authority to promulgate regulations relating to reporting of communicable and noncommunicable diseases from the Disease Prevention and Control Law of 1955 (35 P.S. §521.1 et seq.) (the act). The act provides the Advisory Health Board with the authority to issue rules and regulations on a variety of issues relating to communicable and non-communicable diseases, including which diseases are to be reported, the methods of reporting diseases, the contents of reports and the health authorities to whom diseases are to be reported, what control measures are to be taken with respect to which diseases, and any other matters the Board may deem advisable for the prevention and control of disease, and for carrying out the provisions and purposes of the act. (35 P.S. §521.16(a)). 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 (71 P.S. §541(b)), provides the Advisory Health 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.

Several statutes provide the Department with authority to command disease prevention and control measures within certain institutions. 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. Articles IX and X of the Public Welfare Code (62 P.S. §901-1059), which provide the Department with the authority to license inpatient drug and alcohol abuse treatment facilities, play the same role with respect to the Department's ability to require certain disease prevention and control methods in those facilities.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

The proposed regulation is not mandated by any federal or state law, court order or federal regulation. The Department is mandated to prevent and control the spread of disease by the Disease Prevention and Control Law of 1955. 35 P.S. §521.1, et seq.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The proposed regulation is intended to implement reporting requirements that would provide the Department and local health departments with information sufficient to perform active public health interventions (case tending, referral, counseling, partner notification) and to accurately track the course of the epidemic in the Commonwealth. Being able to identify populations with the disease is important to obtaining federal funding and to allocating resources to efficiently prevent and control its spread.. In the last several years, the number of AIDS cases has declined as a result of improved treatment regimens, since the medical condition of people who are HIV positive may not progress to AIDS as quickly. This means that it takes longer for an HIV positive individual to meet the criteria established by the CDC for being classified an AIDS case. This fact reduces the number of live AIDS cases reported. Since federal funding will soon be determined by the includence of live HIV cases, rather than live AIDS cases, it will become important to be able to provide accurate counts of HIV cases in funding applications. Further, the data collected on AIDS cases now has become less useful as a determinant for prevention planning activities since AIDS data does not accurately show the populations affected. For example, minorities and women are under represented in AIDS incidence data, but are clearly significantly affected populations if HIV data is reviewed. Further, the proposed regulation would allow early intervention by the Department in the medical and social service referral of the patient upon diagnosis of HIV and further enhance linkage to care and referral to a variety of services, including Special Pharmaceutical Benefits Program.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

The Department is the state agency responsible for controlling and preventing the spread of communicable disease. 35 P.S. §521.3(b). This will enhance the Department's ability to develop, implement and evaluate community-based public health interventions for HIV-infected persons and at-risk partners. The proposed information will also provide the Department and local health departments with enhanced opportunities to provide case management services for HIV-infected persons and their at-risk partners. These services include helping assure that HIV-infected persons are linked into appropriate community-based medical and social service support systems, including partner notification services, thus helping slow the progression of HIV infection to life-threatening AIDS and preventing the further spread of disease.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

All citizens of the Commonwealth would benefit from the Department's increased ability to respond to the HIV/AIDS epidemic. A reduction in the number of HIV and AIDS cases should lead to a corresponding reduction in the amount of health care costs. Further, the general health of the Commonwealth would improve. This benefit extends beyond the boundaries of the Commonwealth to citizens of other states since reduction of HIV infection in the Commonwealth will reduce potential exposures to those of other states.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

It is not expected that anyone would be adversely affected by these proposed regulations. Persons with HIV infection, or at risk for HIV, may think they are adversely affected by the proposed regulations, since the proposed regulations would require name reporting. They may, however, choose to go to an anonymous testing site for services. The Department will designate certain public health service sites as anonymous testing sites in accordance with the recommendations of the CDC. Further, the Department believes that the benefit to individual and public health outweighs these concerns.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Laboratories and physicians, hospitals, persons and other entities who diagnose AIDS, or who receive HIV test results or provide HIV and CD4 T-lymphocyte test results to patients would be required to comply with these proposed regulations.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Extensive public meetings were held throughout the Commonwealth to seek the public's input on the need to require HIV as a reportable condition. A total of eight (8) meetings were held, with verbal comments being provided by fifty-six (56) individuals and organizations. Written comments were provided by an additional twenty-eight (28) individuals and organizations who chose not to comment orally.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

There should be no additional costs to the regulated community, since the proposed regulation would only add three additional conditions involving HIV infection to the existing reporting system and clarify that AIDS is to be reported in accordance with the CDC's case definition. The reporting format to be used is the same as the one currently being used by the reporting community to report cases of AIDS. The Department would require persons and entities who report to do so electronically; however, the Department would also provide the software and training to enable these reporters to do so.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

There should be no additional costs to local government since the proposed regulation would only add additional conditions to the existing reporting system. The reporting format to be used is the same as the one currently being used by the reporting community to report cases of AIDS.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulations, including legal and accounting or consulting procedures that may be required.

There will be a cost of $500,000 to the Commonwealth to provide funding for local health departments to increase staff to deal with increasing case loads expected with the implementation of the proposed regulations. These individuals would provide counseling, testing, referral and partner notification services. Prevention activities focused at risk populations would reduce morbidity and could reduce state health care costs.

(20) 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	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS **						
Regulated Community						
Local Government						
State Government						
TOTAL SAVINGS						
COSTS ***						
Regulated Community						
Local Government						
State Government		500,000	500,000	500,000	500,000	500,000
TOTAL COSTS						
REVENUE LOSSES:****						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

***There will be an increase in cost of $500,000 to the Commonwealth for funding to local health departments for additional staff to perform case management functions. There should be no other disease prevention and control costs, as the reporting system is already in place.

An estimate cannot be calculated because savings estimates would have to be based on an assumption that prevention reduces health care costs with a commensurate reduction in disease burden. The Department believes that if the number of cases of HIV can be reduced there will be an accompanying reduction of health care need and expenditures. No estimate can be made to quantify the costs associated with continued or increased HIV morbidity if the proposed regulations are not implemented.

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

Program	1997-98 FY-3	1998-99 FY-2	1999-2000 FY-1	2000-01 Current FY
Bureau of Epidemiology	$2,759,000	$2,702,200	$4,153,829	$4,189,700
Bureau of Communicable Diseases	$49,860,500	$43,035,500	$41,799,921	$40,371,400

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The proposed regulations would create health care cost savings while costing little to implement, since the disease reporting system is already in place. The Department believes that the cost for additional case management positions at the local health departments would allow for a more efficient allocation of prevention and care resources. No estimate of the cost to the public and private health care systems can be made of the costs associated with increased HIV morbidity.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

No nonregulatory alternatives were considered, since the Act requires that diseases and conditions be added to the list of reportable diseases through regulation. The Department is proposing to update its existing regulations, with the approval of the Advisory Health Board, as the Act requires.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered, as the proposed regulations would be an update to existing regulations.

(24) 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 regulation.

There are no provisions that would be more stringent than federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The proposed regulation would allow the Commonwealth to join over 40 other states that have made HIV a reportable disease in some manner. Thirty –four of these states have required confidential name-based reporting. Pennsylvania would be at a disadvantage without the proposed regulations.

Further, the Department has a need to obtain the best data possible to ensure the maximum funding possible for HIV prevention programs, HIV and AIDS treatment programs, and other services. The amount of federal funding for HIV and AIDS care and surveillance programs in the Commonwealth could be jeopardized unless the Department is able to provide in its grant applications for federal funding sufficiently reliable HIV incidence data. The CDC recommended that states implement name reporting of cases of HIV by January 1, 2000. The Commonwealth has not met that recommended deadline.

The Ryan White CARE Act, (42 U.S.C. §§300ff-21 – 300ff-37), one of the Department's primary funding streams for HIV services, requires the inclusion of HIV incidence data in determining the funding formula for state grants. Having accurate data obtained through name reporting will help assure that the Department receives the full funding to which it is entitled.

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

The proposed regulations would offer rulemaking proposed by the Department on May 27, 2000. Those proposed regulations would also amend Chapter 27 (relating to communicable and non-communicable diseases), but would extensively overhaul the entire Chapter.

Because of the importance of adding the conditions in this proposed rulemaking to the list of reportable diseases and conditions, the Department has determined not to wait until those regulations become effective before proposing to add these four conditions.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department has already held public meetings to discuss the issues relating to HIV reporting. It has no further public hearings or information meetings scheduled. A meeting of the Advisory Health Board was held on March 6, 2001 to discuss the proposed regulations; notice of that meeting was published in the Pennsylvania Bulletin. A public comment period of 30 days is included in the proposed regulations.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports that will be required as a result of implementation, if available.

The proposed regulations would add three reportable items to the already existing disease reporting system, and clarify that AIDS is to be reported in accordance with the CDC case definition. The Department proposes to require electronic reporting of laboratories and non-laboratory reporters and will supply "freeware" computer programs to allow for it.

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

There would be no special provisions included in the proposed regulations. Given the nature of disease prevention, the proposed regulations must be applicable to the entire population of the Commonwealth.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The proposed regulations would be final upon publication as final rulemaking in the Pennsylvania Bulletin, with the exception of the reporting duties expressly made effective on January 1, 2002.

(31) Provide the schedule for continual review of the regulation.

The Department will review the proposed regulations as necessary.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
APR 04 2001 DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-166	3/28/01 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)
☐ Check if applicable. Copy not approved. Objections attached.	BY: ROBERT S. ZIMMERMAN, JR. TITLE: SECRETARY OF HEALTH	☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 27]

Reporting of Certain HIV Test Results, CD4 T-Lymphocyte Counts Below a Certain Level, and Perinatal Exposure of Newborns to HIV

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

A. PURPOSE OF THE REGULATIONS

The Department is proposing regulations which would require name reporting of individuals (1) who have had positive test results established from any test approved by the Food and Drug Administration (FDA) to establish the presence of the Human Immunodeficiency Virus (HIV), (2) who have low CD4 T-lymphocyte cell counts as described below, and (3) who are pregnant women who have had positive HIV test results and whose newborns have been perinatally exposed to HIV. The Department also proposes to clarify that that cases of Acquired Immune Deficiency Syndrome (AIDS) are reportable based on the case definition of the Centers for Disease Prevention and Control (CDC). These reports would include presumptive diagnoses of AIDS based on the presence of an AIDS defining illness (for example, Kaposi's sarcoma) with laboratory confirmation of HIV.

The Department's decision to propose regulations requiring reporting of these test results and conditions by name is based on the recommendations of the Centers for Disease Control and Prevention (CDC) for reporting HIV infection and AIDS. See MMWR 1999; 48 (No. RR 13) "Guidelines for Human Immunodeficiency Virus case surveillance, including monitoring for HIV infection and AIDS" (Guidelines) p. 12. It is also consistent with the Department's requirements for the 52 other diseases and conditions (including AIDS which is reportable by name), currently reportable in this Commonwealth. Pennsylvania would join 34 states that require confidential name-based reporting for HIV infection. The Ryan White CARE Act, (42 U.S.C. §§300ff-21 – 300ff-37), one of the Department's primary funding streams for HIV services, requires the inclusion of HIV incidence data in determining the funding formula for state grants. Having accurate data obtained through name reporting will help assure that the Department receives the full funding to which it is entitled.

Collecting this data systematically would provide the Department with the most accurate picture of the prevalence of HIV/AIDS. This will enhance the Department's ability to develop, implement and evaluate community-based public health interventions for HIV-infected persons and at-risk partners. The proposed information will also provide the Department and local health departments with enhanced opportunities to provide case management services for HIV-infected persons and their at-risk partners. These services include helping assure that HIV-infected persons are linked into appropriate community-based medical and social service support systems, including partner notification services, thus helping slow the progression of HIV infection to life-threatening AIDS and preventing the further spread of disease.

BACKGROUND

HIV is a virus transmitted by sexual exposure or exposure to blood or tissue of an infected person. HIV replicates itself within the infected person continuously during the lifetime of the infection, and, in the process, kills white blood cells called CD4 T-lymphocytes. Damage to the immune system occurs because the T-lymphocyte cell count within the body of an infected individual eventually falls below a critical level. The critical level is the point at which the CD4 T-lymphocyte count falls to less than 200 of these cells per 1 microliter of blood, or the CD4 T-lymphocyte percentage of all lymphocytes falls below 14 %. At that point, the individual will almost always lose immune response capabilities and become increasingly susceptible to infection by disease. The late clinical stage of infection with HIV is called AIDS. During the AIDS phase there is progressive damage to the immune and other organ systems, including the central nervous system. HIV infection is generally fatal. There is no vaccination and no cure for HIV infection, although drug therapies have been developed which, when taken appropriately, slow the progression of the disease from HIV to AIDS in many persons.

The seriousness of the HIV/AIDS epidemic should not be underestimated. Because HIV can be spread by individuals who are infected, but do not appear to be ill in any way, and because it is spread, in part, through consensual acts including unprotected sexual intercourse or intravenous needle sharing, controlling the spread of the disease requires active public health measures. Public health efforts to control the disease include encouraging individuals engaging in or subject to behavior which would create a risk of infection to be tested and counseling them, as well as their needle sharing or sexual partners, about how to change risky behavior. Counseling of all persons who are to be tested for HIV infection regarding risk behaviors is required in this Commonwealth (P.L. 585, No. 148) (35 P.S. §§7601-7612) in an effort to educate those persons regarding the danger of continuing to engage in behavior that could put them and others at risk for contracting HIV. Active public health measures also include finding infected individuals, recommending testing and counseling, and offering assistance to private sector providers who may be unaware of the services available to HIV infected patients, or who may have limited experience in dealing with this particular infection.

NEW AND CLARIFIED REPORTING REQUIREMENTS

AIDS defined by the CDC Case Definition

The Department is proposing to clarify that the definition of AIDS is the CDC case definition. The CDC's case definition for AIDS, simply put, includes the presence of HIV infection plus one of several specified infections, conditions, or diseases. Each of the specified infections is an AIDS defining illness. The Department expects the reporting of AIDS in accordance with this case definition.

Positive HIV Diagnostic Test Results

The Department is proposing to require reporting of positive test results of any test approved by the FDA to establish the presence of HIV, including serologic, virologic, nucleic acid (DNA or RNA) or other tests the FDA may approve for that purpose. The HIV test results that the Department is proposing be reported are not preliminary inconclusive HIV tests. Rather, they are either considered to be confirmatory of the presence of HIV, or so reliable that further confirmatory testing is unnecessary. This is in accord with Act 148, which states that no test shall be considered to be positive, and no positive result shall be revealed, without confirmatory testing if that testing is required by generally accepted medical standards (35 P.S. §7605(c)).

CD4 T-Lymphocyte Counts of Less than 200 Cells per Microliter of Blood or T-Lymphocyte Percentage of Less than 14% of Total Lymphocytes

The Department is also proposing reporting of a CD4 T-lymphocyte count of less than 200 cells per microliter or a CD4 T-lymphocyte percentage of total lymphocytes of less than 14%. The Department intends to use the reporting of CD4 T-lymphocyte results to enable it to find cases of HIV and AIDS that might not otherwise be reported. For example, a physician could choose to order a CD4 T-lymphocyte count on an individual and not an HIV test. A low CD4 T-lymphocyte count could be indicative of a suppressed immune system for reasons other than HIV infection. Cancer, for example, could lead to a low CD4 T-lymphocyte count. The Department and local health departments would take this information and, depending upon the circumstances of the case, contact the provider to ask whether that provider has considered ordering an HIV test for the individual in question. Determining that the patient has HIV may cause the provider to refer the individual for more specialized treatment, or enable the provider to offer the individual the opportunity to begin treatment for the disease.

As of January 1, 2001, 27 states required CD4 T-lymphocyte reporting, including New York, New Jersey and Texas. In this Commonwealth, Philadelphia has also instituted a program for reporting CD4 T-lymphocyte counts below a certain level. In New Jersey and Texas, approximately 60% to 70% of CD4 T-lymphocyte reports result in the finding of HIV cases. In California, which also requires CD4 T-lymphocyte reporting, although it does not currently have a requirement that makes HIV reportable, approximately 90% to 95% of reported CD4 T-lymphocyte reports result in HIV and AIDS case finding.

The Department is proposing that both laboratories and providers be required to report CD4 T-lymphocyte test results. The Department would be able to analyze the data obtained through these reports and make determinations about what types of treatment are effective in arresting disease. That information could be shared with the provider community in this Commonwealth.

Requiring reporting of low CD4 T-lymphocyte counts, which reveals dangerous levels of immunodeficiency in the population, fulfills a public health function. Increased

incidence of compromised immune systems in a population as shown by low CD4 T-lymphocyte counts in that population could be indicative of problems in addition to HIV, and could necessitate a public health intervention that focuses on more than HIV infection. For example, a continual decrease in CD4 T-lymphocyte levels could be connected to an increasing incidence of tuberculosis, sexually transmitted diseases and other infections.

Perinatal Exposure of a Newborn to HIV

Newborn infants can be infected with HIV if it is passed to them during pregnancy by an infected mother. The Council of State and Territorial Epidemiologists (CSTE) and the American Academy of Pediatrics (AAP) have recommended that all states and territories conduct pediatric HIV surveillance that includes all perinatally exposed infants. The CDC and CSTE recommend reporting of perinatal exposure to HIV. (Guidelines, p. 11). The CDC notes in its Guidelines that states with confidential name-based surveillance systems have used data on children perinatally exposed to HIV to track the trend of the epidemic in that population. Information these states have collected includes information used to document the sharp decline in perinatally acquired HIV infection in those states, the increase in proportion of infected pregnant women who have been tested before delivery and the high proportion of these women who have accepted treatment before giving birth. (Guidelines, p. 5).

Requiring reporting of the perinatal exposure of newborns to HIV would enable the Department and local health departments to follow up on children known to be exposed to HIV at birth and to ensure that the child and mother are linked to a provider, in case the child is infected with HIV. A child born to a mother infected with HIV will have antibodies to HIV, since the baby will have its mother's antibodies to the virus. However, not all babies born to infected mothers are actually infected with HIV. The departments would be able to follow the child to recommend additional testing to determine whether or not the child is HIV-positive following delivery, and to aid in the referral of that mother and child for treatment.

REPORTING PROCESS

Under the Department's proposed regulations, reports of these four conditions would be made by providers to one of the LMROs, which consist of the Department's 6 district offices and the 10 county or municipal health departments (local health departments). The provider would make the report to the LMRO with responsibility for the geographic area in which the patient was provided testing services, or diagnosed with AIDS.

This differs from the Department's proposed requirement that laboratories report directly to the Department. See proposed amendments to §27.22 (relating to reporting laboratory results indicative of certain infections or conditions). From the standpoint of efficiency, the requirement would provide the information to enable and expedite case tracking and

other services by the local health departments and Department staff that do the actual case investigation and follow-up, and assist in counseling, referral and partner notification.

Laboratory Reporting

The Department has been encouraging electronic reporting to one location by laboratories because many of the laboratory's reports could be reports of repeat tests. Providers will often order repeat CD4 T-lymphocyte tests for purposes of clinical patient care management and disease progression monitoring. Patients may also visit more than one provider and be tested multiple times. The laboratory has no way of knowing whether a test is the initial test a provider orders on a patient or a repeat test, or a test ordered by a second provider. The Department has software to electronically match information in those reports with information from reports it already received and placed in its Statewide reporting databases. The Department can then identify multiple reports on the same individual and consolidate unduplicated useful information in one case record. Local health departments and the Department's district offices do not now have this capability.

Provider Reporting

The Department is proposing to require reporting by physicians, hospitals and other persons and entities, diagnosing AIDS, or providing or receiving reportable HIV or CD4 T-lymphocyte test results. This will undoubtedly generate multiple reports on the same case from various providers and laboratories, as has been discussed. However, the Department does not want possible reporters to self-censor, based on their assumption that another person will make the report. That could lead to under-reporting and jeopardize the ability of the public health system to positively impact the health of infected individuals and their contacts. If the departments are unaware of cases, they will be unable to offer or provide counseling and referral information services to the providers who treated those cases.

Reports being received by LMROs from providers of the diseases and conditions addressed in these proposed regulations would be handled in the same manner as reports of other reportable diseases are currently processed by the Department and local health departments on a local level, with the exception that the Department intends to require that providers as well as laboratories begin to report electronically. As with laboratories, the Department will provide providers with the necessary software package, and make available training on its use.

Once a provider makes a report to the LMRO, that report would be entered into the local database, and matches would be done by the LMRO against local data to eliminate any data on an individual that may be redundant due to an earlier report. For purposes of confidentiality, an LMRO will only have access to reports of cases from that LMRO's jurisdiction. This data would then be transferred to the Department electronically. The

Department would then perform a Statewide match of the information against data included in its Statewide data banks. The information would be returned to the LMRO with any additional information the Department may be able to add to it for case investigation if necessary. This type of match cannot be done exclusively at a county level, since it would not result in the purging of duplicate results collected Statewide. This needs to be done by a single entity having access to Statewide information for the most effective results. Further, performing this type of match at the State level would ensure that the only information sent to the local health departments or district offices by the Department for purposes of follow-up with providers would be a unique report, so that staff do not waste time and resources re-investigating a previously reported case.

Once the case investigation is concluded, the information would be returned to the Department by the LMRO. Following review by the Department, the information would be sent, with identifying information purged, to the CDC for National comparisons.

Dual reporting

A "dual pathway" of reporting, with reports transmitted by both providers and laboratories, is not unique to Pennsylvania. It is the National standard for ensuring completeness of reports in active case investigation for HIV/AIDS, and is utilized in most high and moderate morbidity states comparable to Pennsylvania. Ideally, the diagnosing provider should make the initial case report. Through the identification of providers in laboratory reports, the Department is able to contact providers and obtain from them a completed case report on a particular patient whose test result has been reported to the Department by a laboratory but for whom no report has been made by the provider. This approach is consistent with the CDC and with protocols in other states.

CONFIDENTIALITY

Like all information reported to the Department under the Disease Prevention and Control Law of 1955 (P.L. (1955) 1510) (35 P.S. §§521.1 – 521.21) (Act), the confidentiality of the information reported under these proposed regulations would be strictly maintained by the Department and local health departments. The Act prohibits the Department from releasing information secured pursuant to the statute, even in the face of a subpoena, with few exceptions. Section 15 of the Act provides as follows:

> State and local health authorities may not disclose reports of diseases, any records maintained as a result of any action taken in consequence of such reports, or any other records maintained pursuant to this act or any regulations, to any person who is not a member of the department or a local board or department of health, except where necessary to carry out the purpose of the act. (35 P.S. §521.15).

The Supreme Court of this Commonwealth has stated that the purpose of the Act is to aid the Department and local health departments to prevent and control the spread of disease. See Commonwealth v. Moore, 526 Pa. 152, 159, 584 A.2d 936, 940 (1991). In Moore, the Supreme Court held that release of information collected under the Act to aid a criminal prosecution did not carry out the purpose of the Act. The Department may disclose aggregate information on disease cases for research purposes, but will only do so without including case-identifying information.

The Department will disclose identifying information with a valid consent from the subject whose information is being requested. In the case of HIV and AIDS-related information, that consent would need to comply with the requirements of Section 7 of Act 148 (35 P.S. §7607). Under Act 148, information may not be released by any person who has obtained the HIV-related information in the course of providing a health or social service, except in two instances. First, confidential HIV-related information may be released without a written consent if the person to whom the release is being made fits within 1 of 12 categories of persons specifically listed in Act 148. Release to any other person requires a very specific written consent. Secondly, the subject of the information may consent to its release. (35 P.S. §7607(a)). The consent, however, must include specific requirements listed in Act 148, including a specified time or event upon which the consent is revoked (35 P.S. §7607(c)), and a statement prohibiting redisclosure unless redisclosure is made in accordance with that act. (35 P.S. §7607(e)). A general authorization for the release of medical or other information is not sufficient for the purposes of Act 148. Id.

The Department takes its responsibilities to maintain confidentiality very seriously. The decision to release information would not be made without serious discussion at every relevant level of the Department.

Because the Department and local health departments take the responsibility to protect all information reported under the Act very seriously, it has, on several occasions, engaged in litigation in State and federal court rather than release information reported under the Act. The Department will treat the information that would be reported under these proposed regulations no less carefully than the information it currently protects.

B. REQUIREMENTS OF THE REGULATIONS

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

Section 27.1. Definitions.

The Department is proposing to add several definitions to this section. The Department would add acronyms for "CDC – Centers for Disease Control and Prevention" and "FDA – Food and Drug Administration" so that the acronyms may be used throughout the regulations and readers would understand what they refer to. The Department would define "district office," "LMRO - local morbidity reporting office" and "local health

department" so that when these terms are used in the regulations it will be clear to which health authority the person required to report is to make the report.

The Department is also proposing to add a definition for "perinatal exposure of a newborn to HIV." The Department is proposing to define this reporting requirement so that it is clear that a report should be made if there is any risk to the fetus during any part of pregnancy, regardless of the final outcome of the pregnancy or the final serostatus of the newborn if the pregnancy results in a live birth. This definition would result in more complete reporting of perinatal exposure and also enable the Department to monitor potential adverse effects among women who may have received prenatal preventive antiretroviral treatment including both those who have livebirths, and those who have not carried their pregnancies to full term.

Section 27.2. Reportable diseases.

The Department is proposing to add HIV, CD4 T-lymphocyte test results with counts less than 200 cells/*u*L or less than 14% of total lymphocytes, and perinatal exposure of newborns to HIV to the general list of diseases and conditions required to be reported within the Commonwealth. The Department is proposing to clarify that AIDS is to be reported as defined by the CDC case definition. These requirements would be effective as of January 1, 2002. The Department has already discussed the need for the reporting of these test results and conditions.

This section does not address the type of information needed regarding HIV infection to trigger a reporting responsibility. The Department proposes to address that matter in §27.22 (relating to reporting results indicative of certain infections or conditions by laboratories) and §27.32 (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV by physicians, hospitals, persons or entities, who diagnose AIDS or who receive or provide HIV and CD4 T-lymphocyte test results).

SUBCHAPTER B. REPORTING OF DISEASES

GENERAL

Section 27.21. Physicians who treat patients with reportable diseases including tuberculosis.

The Department is proposing to delete subsection (e) of this section as redundant, since the Department is proposing that all AIDS reporting requirements, including those for physicians, be included in proposed §27.32 (relating to reporting AIDS), which would be amended and retitled "Reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV by physicians, hospitals, persons or entities, who diagnose AIDS or who receive or provide HIV and CD4 T-lymphocyte test results."

Section 27.22. Reporting results indicative of certain infections or conditions by laboratories.

This section addresses the reporting responsibilities of laboratories. Subsection (a) specifies the circumstances under which a laboratory has a duty to report. The Department is proposing to amend subsection (a) to add virologic and nucleic acid (DNA or RNA) to the description of the types of testing information that is reportable. The Department would also replace the word "examination" in this subsection with the word "test," a more accurate term.

The Department is proposing to amend subsection (b) to require laboratories to report CD4 T-lymphocyte test results with counts less than 200 cells/*u*L or a CD4 T-lymphocyte percentage of total lymphocytes that is less than 14%. The Department is also proposing to amend subsection (b) to require laboratories to report HIV. Pursuant to the proposed amendments to §27.2 (relating to reportable diseases), neither a low CD4 T-lymphocyte count nor HIV infection would be reportable by laboratories until January 1, 2002. The type of information to be included in these reports would be specified in subsections (c) and (d). Subsection (d)(5) would clarify that laboratories are to report HIV infection only when the laboratory secures positive results on a test approved by the FDA to establish the presence of HIV. The laboratory would have no duty to report preliminary HIV test results that the FDA does not recognize to be conclusive.

Subsection (c) would be amended to add a paragraph (2), which would set out the demographic information that must be included by the laboratory in its report to the Department of a positive HIV test result or a CD4 T-lymphocyte count. As previously explained, the more specific the information received by the Department from all reporters, the more likely it is that the Department would be able to extract information obtained from all reporting sources and compile a complete record on each reported case.

The Department is proposing to amend subsection (d) to require electronic laboratory reporting directly to the Department's Bureau of Epidemiology for almost all diseases reported by laboratories under Chapter 27. Subsection (d)(1) would be amended to require all reports by laboratories, except for reports of hypothyroidism and phenylketonuria and certain reports of sexually transmitted diseases, to be made electronically to the Bureau of Epidemiology. Hypothyroidism and phenylketonuria are currently, and would continue to be, reported directly to the Department's Division of Maternal and Child Health. Lead and lead toxicity reports, however, which are currently reported elsewhere, would be reported electronically directly to the Department's Bureau

of Epidemiology. See proposed subsection (d)(1). Reports of sexually transmitted diseases would be reported not only to the Department electronically, but also to the local health departments of Allegheny and Philadelphia counties, as they are currently.

For smaller laboratories that are not currently reporting to the Department electronically, and do not have the necessary software, the Department would make software available along with training on its use.

The Department is also proposing to revise subsection (d) to include specific requirements for the reporting of HIV and CD4 T-lymphocyte counts. Subsection (d)(4) would be amended to delete references to lead poisoning and lead toxicity. As revised, subsection (d)(4) would require a laboratory to report CD4 T-lymphocyte counts as set forth in subsection (b) within 5 days of the laboratory obtaining the test result.

Subsection (d)(5), also new, would include requirements for reporting HIV by a laboratory. As discussed previously, a laboratory would be required to report the results of any test approved by the FDA to establish the presence of HIV including serologic, virologic, nucleic acid (DNA or RNA), or other tests approved by the FDA for that purpose. This would include tests such as the ELISA, Western blot, or viral load tests.

New subsection (e) would require a person or entity that requests a laboratory test for HIV or CD4 T-lymphocyte counts to provide the laboratory with all the demographic information the laboratory would be required to include in its report. This promotes completeness of laboratory reporting.

Section 27.32. Reporting AIDS, HIV, CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV, by physicians, hospitals, persons or entities, who diagnose AIDS or who receive or provide HIV and CD4 T-lymphocyte test results.

This section pertains to reporting by persons that are not laboratories. The Department is proposing to replace requirements in the current section for reporting AIDS with more specific requirements for reporting AIDS based on the CDC case definition.This section would require the reporting of the results of any test approved by the FDA to establish the presence of HIV, including serologic, virologic, nucleic acid (DNA or RNA) or any other test that the FDA may approve for this purpose. It would include reporting of CD4 T-lymphocyte counts of a certain level, and reporting of the perinatal exposure of a newborn to HIV. Subsection (a) would require physicians, hospitals and other persons or entities providing HIV services, that make a diagnosis of AIDS, or who receive HIV and CD4 T-lymphocyte test results for patients or provide these results to patients, to report these conditions and test results. In the case of perinatal exposure, reporters would be required to report the name of the mother, with an identification of the child in that report. If the child would then test positive for HIV at a later date, the Department would include that information in its case record for the mother, and a separate case record would be kept under the child's name.

The Department has included persons or entities providing HIV services that receive HIV and CD4 T-lymphocyte test results or provide HIV and CD4 T-lymphocyte test results to patients in the list of required reporters to ensure that the reporting duty applies to all possible persons or entities with relevant information. Entities like case management organizations, drug and alcohol abuse treatment facilities, mobile vans and small clinics that do not have a physician present on a continuous basis would also be required to report under these proposed regulations. Again, this proposed reporting requirement would enable the Department to receive information from the widest range of sources. This proposed reporting requirement is designed to provide, once the case investigations are undertaken, and the data received reviewed to consolidate duplicate case reports into one case record, the most accurate count of all HIV/AIDS cases, and the most complete data possible on each reported case. Nothing in this section should be construed to permit persons to order or receive HIV test results if they are not otherwise authorized by law to do so.

The Department is proposing in subsection (a) that all of the reports that would be added through the proposed amendments to this section be made to the LMRO in the area in which the patient is tested or diagnosed. The LMRO would then report electronically to the Department.

Subsection (b) would include the list of information providers would be required to report. This information would include, among other things, the name of the individual tested.

The Department is also proposing to require reporting of data elements similar to those required to be reported by laboratories, however, the Department would also require the reporting of additional data elements by physicians, hospitals, and other persons and entities, who diagnose AIDS, or receive or provide HIV and CD4 T-lymphocyte test results to patients. These additional elements would include the probable mode of transmission; treatment provided; name, address, and telephone number of the physician, hospital, or other person or entity which secured the specimen from the individual and provided it for testing; name, address and telephone number of the entity in which the diagnosis was made, or by which the HIV test results or CD4 T-lymphocyte counts were received; and any other information the Department determines to be relevant. This information would not be readily available to laboratories, but would be available to providers. Like the information that would be required of laboratories, this information would provide the Department with a specific demographic picture of the individual, and enable the Department to track the trends of the disease throughout the Commonwealth. The information would also enable the Department to more easily contact the provider treating the patient, and provide that individual with information regarding the disease, help in counseling and partner notification, and referral options.

Subsection (c) would require providers to report to the Department within 5 business days of the reportable diagnosis or receipt of the test result. The Department would probably receive the laboratory reports before the provider received them. The

Department proposes allowing this 5-day period to enable the provider to provide results to the patient, and to begin the process of counseling and referral, before reporting to the LMRO. The Department would be available after that period (or before if requested by the provider to perform results counseling) to aid the provider by providing information regarding the disease if that is requested, to perform partner notification if the patient is willing, and to provide information regarding referral options and services open to the patient, for example, the Special Pharmaceutical Benefits Program.

Subsection (c) would also require providers to make reports to the Department electronically. In addition to the electronic report, the Department is also proposing to require that providers maintain in the patient file a hard copy of the HIV/AIDS report form provided by the Department and completed by the provider. This would aid the departments in case investigation and follow-up if there is a need to review the patient file, as well as in reviewing compliance with reporting requirements under the proposed regulations.

The substance of new subsection (d) is substantially contained in current subsection (b). Minor revisions would be made to replace the phrase "local health authority" with "LMRO" and to require that reports be made electronically.

As proposed in §27.2 (relating to reportable diseases) neither a low CD4 T-lymphocyte count, a positive test result on a test establishing the presence of HIV, or a perinatal exposure of a newborn to HIV would be reportable, until January 1, 2002. The Department also proposes that its clarification regarding reporting of AIDS based on the CDC case definitionbecome effective on that same date.

Section 27.32a. Confidential and anonymous testing.

This section would be new. Subsection (a) would require testing done at sites other than State-designated anonymous testing sites to be done confidentially but not anonymously. Anonymous testing is testing done without the tester obtaining the name of the individual being tested. The Department is making anonymous testing sites available in accordance with CDC recommendations, and to avoid creating a situation in which those at-risk individuals who would refuse to be tested confidentially would simply not be tested and, therefore, continue to place themselves and others at risk.

However, because the Department believes that name reporting is a very important component of the public health strategy as outlined by the CDC for addressing the disease, the Department is limiting anonymous testing to Department-designated sites. The Department and local health departments are able to become involved in counseling, partner notification, and referral in these public sector testing sites without name reporting, since the individual has physically come into the public health system funded and, in some cases, operated by the departments.

The results of blinded HIV testing authorized under section 5(f) of Act 148 (35 P.S. §7605(f)) would not be reportable under this proposed section. See proposed subsection (a).

Subsection (b) would require anonymous test sites to report results to the Department in accordance with proposed §27.32 using an anonymous code rather than the name of the individual. The code would be assigned at the anonymous testing site, using a Department-approved algorithm.

Section 27.32b. Counseling, testing, referral and partner notification services.

This section would be new. It would require that counseling, testing, referral and partner notification services be done in accordance with the requirements of Act 148. It is proposed for the purpose of emphasizing the connection between Act 148 and the Act to ensure that all confidentiality requirements are followed, and to stress that nothing in the proposed regulations is to be construed in a manner inconsistent with Act 148. The Department has also proposed language reminding providers that the Department will provide assistance with counseling, testing, referral and partner notification if requested.

Section 27.32c. Department authority to require complete reporting.

This section would be new. The Department has, in the past, encountered resistance from providers who hesitate to allow Department staff to review patient records in order to complete case investigations for reportable diseases and conditions. The Act gives both the Department and local health departments the authority to undertake these reviews. Sections 3 and 5 of the Act give the Department and the local health departments the responsibility for the prevention and control of the spread of disease (35 P.S. §521.3(a) and (b)) and the authority to take any disease control measure necessary to protect the public health upon receipt of a report of a disease (35 P.S. §521.5). Section 16 of the Act gives the Department, through the Board, the ability to promulgate whatever regulations are necessary to prevent and control the spread of disease (35 P.S. §521.16(a) and (b)). Further, the Administrative Code of 1929 gives the Department the ability to take the most efficient and practical means necessary for the prevention and suppression of disease (71 P.S. §532(a)). Since the reviews proposed in this section are necessary for locating cases and controlling and preventing the spread of disease, the Department and local health departments are authorized by the Act to undertake the reviews, and to promulgate regulations concerning those reviews.

Further, since section 4 of the Act (35 P.S. §521.4) places reporting responsibilities on certain persons, and section 16(a) and (b) (35 P.S. §521.16(a) and (b)) gives the Department the authority to promulgate regulations to effectuate these reporting requirements, the Department has the authority to review these records to ensure that reporting is occurring appropriately.

Proposed subsection (a) would clearly state this authority to eliminate further confusion on the part of providers. Subsection (b) would clarify the Department's authority to require special reports from providers and laboratories in order to ensure reporting compliance.

Section 27.32d. Record audits.

This section would be new. The Department is proposing to review records of physicians, hospitals, and other persons or entities, who diagnose cases of AIDS, or provide or receive HIV and CD4 T-lymphocyte test results. The Department's audit would extend back to January 1, 2000. These audits would allow the Department to collect information to complete HIV and CD4 T-lymphocyte case reports, enabling it not only to track disease trends, but to complete case investigations and obtain information necessary to complete applications for federal funding grants from the CDC and from the United States Department of Health and Human Services (HHS). The Ryan White CARE Act Amendments of 2000 ((Pub. L. 106-345) (114 Stat. 1319, 1323-1325)) require the Secretary of the federal agency of Health and Human Services to determine by July 1, 2004, if HIV case data provided by states is sufficiently accurate and reliable to use in the grant formula. If it is not, the Department will be able to use only live AIDS case data in its fiscal year 2005 (April 1, 2005 to March 31, 2006) application for grant allocations. Because AIDS case numbers have fallen, as discussed above, this could decrease the amount of funding received by the Commonwealth. The Department is proposing this review of case information back to January 1, 2000, to ensure that it has the most accurate and reliable data available.

C. AFFECTED PERSONS

These proposed regulations would affect physicians, hospitals and other persons or entities providing HIV services, who diagnose AIDS or who provide or receive HIV and CD4 T-lymphocyte test results. They will be required to report diagnosed cases of AIDS, HIV test results, low CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV. The regulations would also affect laboratories, which will be required to report certain positive HIV tests and CD4 T-lymphocyte counts of a certain level.

The proposed regulations would also affect local health departments that are involved in the reporting system, particularly the local health departments for Allegheny and Philadelphia Counties, which are currently considering or which have already implemented CD4 T-lymphocyte reporting. The regulations would also impact persons with AIDS, persons with HIV infection and at risk for contracting HIV, persons with low CD4 T-lymphocyte counts, and pregnant women at risk for HIV or who test positive for HIV, and their newborn children. Required reporting of the conditions and test results included in this proposed rulemaking would permit the Department to obtain more accurate information regarding the trends of the disease, and therefore to target funding to programs that would provide maximum benefit to these individuals. Further, reporting of

cases to the Department would enable public health professionals to provide counseling, testing, and referral to infected persons, and with the individual's permission, to conduct contact tracing which can lead to early detection and treatment.

D. COST AND PAPERWORK ESTIMATE

1. Cost

The proposed amendments would have no measurable fiscal impact on local government, the private sector or the general public, because the disease reporting system already exists in this Commonwealth. There would be an increase in cost of $500,000 to the Commonwealth, since the Department anticipates spending that amount for additional positions in the 10 local health departments for staff to carry out case management activities, including counseling, testing, referral, and partner notification. The Department anticipates this increase in personnel would be necessary because of the increase in the number of actual cases that would be seen once the addition of the conditions proposed by this rulemaking to the list of reportable diseases becomes final. The Department believes that this increase in cost to the Commonwealth would be outweighed by the savings from this proposed regulation, caused by reporting of information that would enable the Department to focus prevention efforts on the most at-risk populations. Over time these activities should cause a reduction in the number of HIV cases in the Commonwealth. This would reduce health care costs.

No additional cost would accrue from the Department's provision of software for electronic reporting, since the Department obtains that software for these purposes free-of-charge from the CDC. It is anticipated that any additional modification to the software necessary to suit the Department's purposes would be done either in-house or at no additional charge to the Department by current contractors.

2. Paperwork Estimates

Because the disease reporting system is already in place in the Commonwealth, the addition of other diseases and conditions to the list of reportable diseases and conditions should create no measurable increase in paperwork. Cases of HIV, low CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV would be reported and investigated in a similar manner to cases of currently listed diseases, infections, and conditions using National case definitions and a reporting format similar to that currently used to report AIDS. The Department is requiring electronic reporting, but is offering the software to those required to report free-of-charge.

E. STATUTORY AUTHORITY

The Department obtains its authority to promulgate regulations relating to reporting of communicable and noncommunicable diseases from the Act. The Act provides the

Advisory Health Board with the authority to issue rules and regulations on a variety of matters relating to communicable and noncommunicable diseases, including which diseases are to be reported, the methods of reporting diseases, the contents of reports and the health authorities to whom diseases are to be reported, what control measures are to be taken with respect to which diseases, and any other matters the Board may deem advisable for the prevention and control of disease, and for carrying out the provisions and purposes of the Act. (35 P.S. §521.16(a)). 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 (Code) (71 P.S. §51 et seq.) Section 2102(g) of the Code (71 P.S. §532(g)) gives the Department this general authority.

Section 2111(b) of the Code (71 P.S. §541(b)) provides the Advisory Health 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.

Several statutes provide the Department with authority to command disease prevention and control measures within certain institutions. 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 that certain actions relating to disease control and prevention occur within health care facilities. Articles IX and X of the Public Welfare Code (62 P.S. §§901-1059), which provide the Department with the authority to license inpatient drug and alcohol abuse treatment facilities, play the same role with respect to the Department's ability to require certain disease prevention and control measures in those facilities.

F. EFFECTIVENESS/SUNSET DATES

The proposed regulations will become effective upon publication of final rulemaking in the *Pennsylvania Bulletin*, with exception of the reporting duties expressly made effective on January 1, 2002. 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 (71 P.S. §§745.1-745.15), the Department submitted a copy of this proposed regulations on April 10, 2001, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department within 10 days of the close of the Committees' review period. The notifications shall specify the regulatory review criteria, which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation by the Department, the General Assembly and the Governor, of objections raised.

H. CONTACT PERSON

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Joel H. Hersh, Director, Bureau of Epidemiology, Department of Health, P.O. Box 90, Harrisburg, PA 17108, (717) 783-4677, 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 Mr. Hersh so that necessary arrangements may be made.

ANNEX A

TITLE 28. HEALTH AND SAFETY

* * *

PART III. PREVENTION OF DISEASES

* * *

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

§27.1. Definitions.

* * *

CDC – Centers for Disease Control and Prevention.

* * *

District office. – One of the district headquarters of the Department located within this Commonwealth.

* * *

FDA – Food and Drug Administration.

* * *

LMRO – Local morbidity reporting office – A district office of the Department or a local health department.

* * *

Local health department. – Each county department of health under the Local Health Administration Law (16 P.S. §§12001-12028), and each department of health in a municipality approved for a Commonwealth grant to provide local health services under section 25 of the Local Health Administration Law (16 P.S. §12025). The Department will maintain a list of local health departments and revise the list when new local health departments are established.

* * *

Perinatal exposure of a newborn to HIV – The subjecting to risk of HIV infection of a fetus during the pregnancy of an HIV-positive woman regardless of the final outcome of the pregnancy or the final serostatus of the newborn if the pregnancy results in a live birth.

* * *

§27.2. Reportable diseases.

The Board declares the following communicable diseases, unusual outbreaks of illness, noncommunicable diseases and conditions to be reportable:

AIDS (Acquired Immune Deficiency Syndrome) as defined by the CDC case definition (effective January 1, 2002).

* * *

CD4 T-lymphocyte test result with a count of less than 200 cells/*u*L or less than 14% of total lymphocytes (effective January 1, 2002).

* * *

HIV (Human Immunodeficiency Virus) (effective January 1, 2002).

* * *

Perinatal exposure of a newborn to HIV (effective January 1, 2002).

* * *

SUBCHAPTER B. REPORTING OF DISEASES

§27.21. Physicians who treat patients with reportable diseases including tuberculosis.

* * *

[(e) Physicians shall report cases of AIDS under §27.32 (relating to reporting AIDS).]

§27.22. **Reporting [laboratory] results indicative of certain infections or conditions by laboratories.**

(a) A person who is in charge of a laboratory in which a laboratory [examination] test of a specimen derived from the 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 listed in subsection (b) shall report promptly the findings, not later than the next working day after the close of business on the day on which the [examination] test was completed, except as noted otherwise in this chapter.

(b) The conditions or diseases to be reported include the following:

* * *

CD4 T-lymphocyte test result with a count of less than 200 cells/*u*L or less than 14% of total lymphocytes.

* * *

HIV (Human Immunodeficiency Virus).

* * *

(c) Reports shall include the following information:

(1) *Reports of test results other than HIV and CD4 T-lymphocyte test results.* The report shall give the name, age and address of the person from whom the specimen was obtained, and the name and address of the physician for whom the examination or test was made.

(2) *Reports of HIV and CD4 T-lymphocyte test results.* Laboratories shall report electronically to the Department's Bureau of Epidemiology. 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 by the physician or at the facility requesting the laboratory test.

(iii) The individual's date of birth (month, day, year).

(iv) The individual's sex.

(v) The individual's race/ethnicity.

(vi) The date of each test performed.

(vii) The type of test or tests performed.

(viii) The results of the tests.

(ix) A CD4 T-lymphocyte test result with a count of less than 200 cells/*u*L or a CD4 T- lymphocyte percentage of less than 14% of total lymphocytes.

(x) The name of the person or entity submitting the specimen for testing.

(xi) The address of the person or entity submitting the specimen for testing, including the zip code, physical address and telephone number of the submitter.

(d) The [report shall be submitted by the] person in charge of a laboratory shall submit the report as follows:

(1) *Reports except for venereal diseases, hypothyroidism in infants up to 24 months old*[,] and *phenylketonuria* [*and lead poisoning or lead toxicity*. Reports shall be made to the appropriate health authority of Philadelphia, or the county department of health if the patient resides in such an area. Other reports shall be sent to the Division of Epidemiology, Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108]. Laboratory test results shall be reported directly to the Department's Bureau of Epidemiology through secure electronic mechanisms in a manner specified by the Department.

(2) *Veneral disease (including positive dark fields).* Reports shall be made to the appropriate health authority of Philadelphia when the patient resides in Philadelphia and to the health authority in Allegheny County when the patient resides in Allegheny County. Other reports shall be sent to the [Division of Communicable Disease Control and Surveillance, Bureau of Epidemiology and

Disease Prevention, Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108, unless otherwise directed by the Secretary] Department as required in paragraph (1).

* * *

(4) [*Lead poisoning or lead toxicity.* Reports shall be made to the Division of Environmental Health, Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108-9990 on forms developed and supplied by the Division of Environmental Health.]

Reports of CD4 T-lymphocyte test result. A laboratory shall report to the Department CD4 T- lymphocyte test result under subsection (b) within 5 days of obtaining the test result.

(5) *Reports of HIV.* A laboratory shall report to the Department positive 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 within 5 days of obtaining the test result.

(e) 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 shall provide to the laboratory the information listed in subsection (c)(2), with the exception of paragraphs (vi) through (ix). In addition to the information included in subsection (c)(2), a person or entity that requests a laboratory test for HIV or a CD4 T-lymphocyte count shall provide to the laboratory the date each test was requested, and the type of test or tests requested.

* * *

§27.32. **Reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV by physicians, hospitals, persons or entities, who diagnose AIDS or who receive or provide HIV and CD4 T-lymphocyte test results.**

[(a) Physicians and hospitals shall report cases of AIDS promptly to the Department of Health, Division of Acute Infectious Disease Epidemiology, Post Office Box 90, Harrisburg, Pennsylvania 17108 or to the local health department in the counties of Allegheny, Bucks, Chester, Erie and Philadelphia and in the cities of Allentown, Bethlehem and York when the individual who is the subject of the report is a resident of the county or city.

(b) Local health authorities receiving reports of AIDS shall forward completed case report forms to the Department of Health in a timely manner. Completed forms shall provide identifying information, including but not limited to, the name of the case, the individual's address and telephone number, the name of the individual's medical provider and the reporting source.]

(a) A physician, hospital, or person or entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV or CD4 T-lymphocyte test results or provides HIV or CD4 T-lymphocyte test results to patients shall report the following to the LMRO responsible for the geographic area in which the person is tested or diagnosed:

(1) A diagnosis of AIDS based on the CDC case definition.

(2) 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.

(3) A CD4 T-lymphocyte test result with a count of less than 200 cells/*u*L or a CD4 T- lymphocyte percentage of less than 14% of total lymphocytes.

(4) A perinatal exposure of a newborn to HIV.

(b) A report of an HIV test result, CD4 T-lymphocyte count, AIDS case based on the CDC case definition, or perinatal exposure of a newborn to HIV shall include the following information:

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

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

(3) The individual's date of birth.

(4) The individual's sex.

(5) The individual's race or ethnicity.

(6) The date of each test performed.

(7) The type of test or tests performed.

(8) 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.

(9) A CD4 T-lymphocyte test result with a count of less than 200 cells/*u*L or a CD4 T- lymphocyte percentage of less than 14% of total lymphocytes.

(10) The probable mode of transmission.

(11) The treatment provided.

(12) The name, address, and telephone number of the physician, hospital, or other person or entity that secured a specimen from the individual and submitted it for laboratory testing.

(13) The name, address and telephone number of the entity in which the diagnosis was made, or that received the HIV test result or CD4 T-lymphocyte count.

(14) Any other information the Department determines to be relevant.

(c) The reporter shall maintain the data required in subsection (b) in the patient file on the Department's HIV/AIDS report form. In addition to completing that form, the reporter shall transmit the report electronically to the LMRO through a secure electronic mechanism specified by the Department within 5 business days of the diagnosis of AIDS or receipt of the results of the test.

(d) An LMRO receiving reports of diagnoses of AIDS, positive HIV test results, reportable CD4 T-lymphocyte counts, and perinatal exposures to HIV shall forward completed case reports containing the information included in subsection (b) electronically to the Department's Bureau of Epidemiology.

§27.32a. Confidential and anonymous testing.

(a) Anonymous testing for HIV, except for blinded HIV testing authorized under §5(f) of the Confidentiality of HIV-Related Information Act (35 P.S. §7605(f), may only be provided at State-designated anonymous testing sites. Anonymous testing is testing provided to an individual

without collecting the individual's name. All other HIV testing shall be conducted confidentially with the name of the tested individual collected, and the name of the individual reported when the result of the test is reportable. Persons or entities reporting as required in this section shall offer all HIV and AIDS-related services confidentially and may not provide anonymous testing, or consider any test or its results to be anonymous.

(b) Anonymous test results shall be reported in accordance with §27.32 (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV by physicians, hospitals, persons or entities, who diagnose AIDS or who receive or provide HIV and CD4 T-lymphocyte test results) without a patient name but with an anonymous code assigned at the time the specimen is collected in accordance with a Department-approved anonymous test site algorithm.

§27.32b. Counseling, testing, referral and partner notification services.

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) (Act 1990-148). A person providing HIV test results to a patient may ask for the Department's assistance with counseling if the person chooses to do so, and if doing so would not violate Act 1990-148.

§37.32c. Department authority to require complete reporting.

To conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays, and to investigate other reporting problems the Department shall have access to and may review the patient records of physicians, hospitals, and other persons and entities providing HIV services, who make diagnoses of AIDS or who receive or provide HIV and CD4 T-lymphocyte test results,

§27.32d. Record audits.

(a) The Department may conduct record audits of the records of physicians, hospitals, and other persons and entities providing HIV services, who make diagnoses of AIDS, or who receive or provide HIV test results for the purpose of obtaining information allowing the Department to complete HIV and CD4 T-lymphocyte 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 ensure compliance with this chapter.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

April 10, 2001

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
333 Market Street
Harrisburg, PA 17101

Re: Department of Health Proposed Regulation No. 10-166
Reporting of Certain HIV Test Results, CD4 T-Lymphocyte Counts
Below a Certain Level, and Perinatal Exposure of Newborns to HIV

Dear Mr. Nyce:

Attached are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). The proposed regulations amend the Department of Health's regulations relating to communicable and noncommunicable diseases (28 Pa. Code Ch. 27) to add reporting of HIV infection, perinatal exposure of newborns to HIV, and CD4 T-lymphocyte cell counts below a certain level. These proposed regulations are being promulgated under the Disease Prevention and Control Law of 1955 (35 P.S. §521.1 et seq.).

Section 5(g) of the Regulatory Review Act (71 P.S. §745.5(g)) provides that the Commission shall, within 10 days after expiration of the Standing Committee review period, notify the proposing agency of any objections to the proposed regulations. The Department expects the regulations to be published on April 21, 2001. 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 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 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 Deborah Griffiths, Director of the Office of Legislative Affairs at (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 10-166

SUBJECT: Reporting of Certain HIV Test Results, CD4 T-Lymphocyte Counts Below a Certain Level, and Perinatal Exposure of Newborns to HIV

AGENCY: Department of Health

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
4/10/01	Marjorie Lelliter	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
4/10/01	April Rucker	
4/10	Krista Kreiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
4/10		
4/10/01	Stephen J. Hoffman	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

April 4, 2001