THE TOLLED REVISED PREAMBLE AND ANNEX ARE ATTACHED AT THE END OF THE REGULATION

Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	2012 MAY 15 PM 3:14 IRRC Number: 2185
(2) I.D. Number (Governor's Office Use) No. 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?
Proposed Rulemaking	X No
X 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 amending regulations to require name reporting of individuals (1) who have been diagnosed with 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 regulations 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 amendments are not mandated by any federal or state law, court order or federal regulation. However, 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 due to improved treatment options, this federal requirement could decrease the amount of funding received by the Commonwealth, unless the Department is able to provide sufficiently accurate data on HIV cases. Name-reporting will enable the Department to do so.

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 regulations implement reporting requirements that provide the Department and local health departments with information sufficient to perform active public health interventions (case management, 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 is 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 amendments 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). The amendments enhance the Department's ability to develop, implement and evaluate community-based public health interventions for HIV-infected persons and at-risk partners. The information collected also provides 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 will 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 will 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 will be adversely affected by these regulations. Persons with HIV infection, or at risk for HIV, may think they are adversely affected by the regulations, since the amendments 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. Many of these sites currently exist, for example, the 57 state health centers, and the contracted providers in the three counties in which the Department does not have a state health center (Dauphin, Berks, and Butler). 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 are required to comply with these 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 prior to the development of the regulations. 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 that chose not to comment orally. Following the publication of the regulations, the Department accepted comments again during a written public comment period, and has considered all the comments it received.

(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 are no additional costs to the regulated community, since the amendments 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 is requiring persons and entities that report to do so electronically; however, the Department is also providing 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 amendments 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 is 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 amendments. These individuals provide counseling, testing, referral and partner notification services. Prevention activities focused at risk populations will reduce morbidity and thus will 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 is 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 are no other contemplated 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 regulations are not implemented.

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

Program	1998-1999 FY-3	1999-2000 FY-2	2000-2001 FY-1	2001-2002 Current FY
Bureau of Epidemiology	$2,702,200	$4,153,829	$4,382,900	$6,828,100
Bureau of Communicable Diseases	$43,035,500	$41,799,921	$40,371,400	$42,090,800

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

The amendments 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 allows 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 amending its existing regulations, with the approval of the 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 amendments are 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 are 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 amendments 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 is at a disadvantage without the amendments.

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 will 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 regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The amendments affect rulemaking proposed by the Department on May 27, 2000. Those proposed regulations were intended to extensively overhaul Chapter 27 (relating to communicable and non-communicable diseases).

Because of the importance of these amendments, the Department determined not to wait until those proposed regulations became final before proposing this rulemaking. The amendments at 30 Pa. B. 2715 (May 27, 2000) have since become final, and these amendments are designed to work within the structure of that final rulemaking.

(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 Board was held on September 26, 2001 to discuss this final rulemaking; notice of that meeting was published in the Pennsylvania Bulletin. IRRC and the Standing Committees may, if they choose, hold public hearings once the Department submits the final form regulations to them.

(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 amendments 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 is requiring electronic reporting of laboratories and non-laboratory reporters and will supply "freeware" computer programs to allow for that to occur.

(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 are no special provisions included in the amendments. Given the nature of disease prevention, the amendments 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 amendments will be final upon publication as final rulemaking in the Pennsylvania Bulletin, with the exception of the reporting duties expressly made effective 90 days after publication.

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

The Department will review the regulations as necessary.

FACE SHEET
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WITH THE LEGISLATIVE REFERENCE BUREAU

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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 _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-166	5/1/02 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
9 Check if applicable. Copy not approved. Objections attached.	BY: ROBERT S. ZIMMERMAN, JR. TITLE: SECRETARY OF HEALTH	9 Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 27]

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

A. PURPOSE AND BACKGROUND

The Department's regulations 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 herein, or (3) who are pregnant women who have had positive HIV test results and whose newborns have been perinatally exposed to HIV. The regulations also clarify that cases of Acquired Immune Deficiency Syndrome (AIDS) are reportable based on the case definition of the Centers for Disease Prevention and Control (CDC). Reports of AIDS include reports of presumptive diagnoses of AIDS based on the presence of an AIDS defining illness (for example, Kaposi's sarcoma) with laboratory confirmation of HIV.

In holding to its proposal to require reporting of these conditions and infections by name, the Department is following recommendations of the 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. Reporting by name 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 joins 34 other 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 provides 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 information also provides 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.

B. SUMMARY

The majority of comments the Department received on its proposed regulations dealt with the Department's decision to require reporting by name. Other general comments were received on a variety of topics: the Department's decision to require reporting

electronically; the confidentiality and security of the information reported; the cost of the proposed rulemaking, and the lack of an exception in the proposed regulations to name reporting for research projects. The Department will discuss these general comments before addressing comments addressed to specific provisions of the proposed regulations.

The Department's rulemaking relating to HIV reporting and the other reporting addressed in these regulations is a very specific amendment to its broader regulations governing prevention, control and reporting of communicable and noncommunicable diseases within the Commonwealth. The Department proposed sweeping changes to update the entire regulatory scheme relating to communicable and noncommunicable diseases (28 Pa. Code Chapter 27) in May of 2000 (30 Pa. B. 2715 (May 27, 2000)). Final rulemaking followed and those amendments went into effect on January 26, 2002. Because of the importance of HIV reporting to the Commonwealth, the Department could not wait to propose additional amendments to Chapter 27 relating to HIV reporting until after the adoption of the broad changes to Chapter 27.

The timing of the Department's proposed rulemaking relating to HIV reporting, therefore, required that the Department propose changes to Chapter 27 as it read prior to the January 26, 2002 amendments. Consequently, in most cases, the text of regulations to which the Department is now adopting amendments is not the same text to which the Department proposed amendments.

In response to a comment from the Independent Regulatory Review Commission (Commission) asking how the Department would coordinate the two sets of rulemaking, and upon advice from the Commission, the Department has drafted Annex A to show only amendments to the current text of regulations that were altered following the proposed rulemaking. Amendments to those regulations that were not revised following proposed rulemaking are shown in the customary fashion. The preamble explains when an amendment is made to a regulation, or the text of a regulation, other than that to which the amendment was proposed.

Name reporting

The Department received many comments objecting to its proposal to require reporting by name of perinatal exposure of newborns to HIV, certain HIV test results and CD4 T-lymphocyte cell counts. These comments came from various groups of persons as well as individuals, including providers, legislators, one local health department, and public interest groups.

The Department also received comments in support of its proposed regulations. Various professional medical associations, provider groups, local health departments, and public interest groups supported the Department's proposal to require reporting by name. The Health and Welfare Committee of the Pennsylvania State Senate supported the proposals contingent upon the Department taking appropriate steps to make anonymous testing a readily available option to those who might otherwise avoid HIV testing, and ensuring that information regarding anonymous testing is available to at risk populations.

The Department has listed the comments both in opposition to and in support of confidential name reporting below, eliminating repetitive remarks where possible, and has answered these comments in one comprehensive response.

Comments in opposition

The Department should justify the need for names and addresses of individuals in the reports and then explain how the reports will be maintained.

Research shows that requiring name reporting deters people from taking HIV tests. Requiring name reporting will undermine hard work done in the Delaware Valley to encourage people to access HIV services. There are 10 states and territories that have chosen to require reports by unique identifier, including Maryland, Vermont, Illinois and California, and this method of reporting does provide accurate data.

Name reporting will delay treatment. The outcry by medical providers, service providers and people living with HIV/AIDS is telling. It is inconceivable that name reporting will not harm lives.

HIV reporting is necessary, but not by name. The Allegheny County Health Department's approach of requiring reporting by unique identifier is better, and should be followed.

Name reporting, even with the availability of anonymous test sites, frightens people, and will deter persons from getting tested, because they are not convinced that confidentiality can be assured.

Name-based reporting will cause women to refuse or forgo prenatal care. This is a concern because convincing pregnant women to take an HIV test has reduced the number of vertical transmissions of HIV.

The Department should explain why a reporting system based on unique identifiers will not accomplish its objectives. Supporters recognize that anonymous testing should augment name-based reporting. But a unique identifier system would reduce the need for anonymous testing.

The CDC recognizes that a unique identifier system will provide necessary information to the public health system to control the spread of disease. The Department should institute a unique identifier system.

Because peer review publications are evenly split on the question of whether persons will be deterred from testing by required name reporting, the Department should err on the side of caution and develop a unique identifier system.

A unique identifier system would protect the confidentiality of persons living with HIV while also providing effective tracking of the epidemic. Pennsylvania could benefit from the California experience where reporting is done by a unique identifier.

A unique identifier system will not cause the Department to lose funding. The Department will only lose funding if no information is reported by the Department to the Federal government. Funding will be a problem under a name reporting system, because, if less people choose to be tested, the Department will have less cases to report. The Department must set up a system that encourages the maximum number of persons to be tested.

Reporting by unique identifier in the initial phase of the continuum of care provides the most precise data available, ensuring that credible information is secured for planning and capturing maximum funding resources.

Although some reported figures show "improved" statistics regarding HIV cases after name reporting is instituted, these figures are misleading. Most often this methodology followed a period of no required reporting, so an improvement in statistics would occur as a matter of course.

The Department's decision to propose name reporting as the method by which cases of HIV would be reported goes contrary to public testimony offered at the Department's

meetings. Ninety-five percent of the people at those public meetings opposed name reporting.

Reporting by name will increase the potential for breaches of confidentiality. Discrimination could occur if the security and confidentiality of information maintained by the Department was breached in some way.

Disenfranchised populations will not be tested if there is the slightest indication that their names could become public knowledge. This will harm the most marginalized populations, including, for example, persons who use illegal drugs.

Name reporting threatens the right to privacy.

Name reporting interferes with the physician-patient relationship.

Comments in support

Confidential name reporting will enhance the Department's opportunities to provide case management services to patients, including getting patients into more services and tracking them to determine quality of care, without fear of breach of confidentiality.

The Department has been thorough in its review of the benefits and shortcomings of reporting based on names and on unique identifiers. The Department has prudently made

the determination that name reporting is the best option, based on public health reasons. Public perception and fear should not drive policy.

Name reporting in delivering direct medical and respite care allows medical professionals to treat HIV clients in the same manner as clients treated for all other communicable diseases, providing the same standard of care.

The Department is to be commended for providing assistance to local health departments through the implementation of these regulations. Name-based reporting will give local health departments information that they now have to guess at. Name-based reporting allows provision of case management services to infected persons and their partners.

The product of ongoing and systematic collection of the information that will result from name-reporting is valid, timely and complete data, and is the key facet to any disease surveillance system. The problem in the Commonwealth has been the fact that HIV was not reportable, despite the fact that sound epidemiologic principles and public health practice necessitates the reporting of communicable diseases that are a public health concern. A name-based reporting system of people with infectious diseases has great potential to benefit both the individual and the public health system. A name-reporting system would result in more people benefiting from early intervention programs.

In a unique identifier system, persons tested anonymously supply in a code, parts of the name, social security number, date of birth, sex and race. The non-name identifier

system is not anonymous as it may be possibly linked to a specific individual. To do record follow-up for missing information, such as HIV-risk, or to provide follow-up care, coded records need to be linked to an individual's name. This is usually found in a log maintained by providers or other reporting sources. Multiple logs with names may create multiple opportunities for breaches of confidentiality.

Name-based reporting would enable public health employees to find and counsel people who are tested but do not return for their results; would enable public health employees to interview clients to assess their need for a variety of community services, including, for example, housing, transportation, medical treatment, tuberculosis testing, and other assistance; could aid partner notification programs; and would aid public health employees in educating HIV-infected women about the risks of pregnancy, and how to minimize the risks of transmission.

Data from a 1998 study of the implementation of name-based HIV reporting in Louisiana, Nevada, New Jersey, Tennessee, Michigan and Nebraska indicated that the impact of surveillance on those seeking HIV testing will be small, and should not hinder HIV prevention efforts.

The impact of HIV-reporting by name is likely to vary from community to community, and risk group to risk group. What matters, however, is that prevention practices can help someone, somewhere, at sometime, and this can only happen with name-based reporting. To allow the Commonwealth to target programs and resources most

effectively, the public health system must keep pace with where the HIV epidemic is going. Improvement of the ability to track early HIV infection before it progresses to AIDS is essential.

The Department should be congratulated for its strong leadership in the face of opposition. Only confidential name-based reporting has the capability of contributing to the control of HIV transmission. The Department can perform contact tracing and partner notification, assist in linkages to treatment and other services, including prevention, case management, and assistance with medication compliance. Name-reporting allows the Department to provide outreach to infected persons, obtain risk factor history information, eliminate duplicate reports and monitor disease trends.

The Department can be trusted to use every mechanism available to it to ensure the confidentiality of reported information, as it has done with information reported on AIDS patients.

Confidential name-based reporting is similar to other reporting requirements in the Commonwealth, and follows the recommendations established by the CDC. The Commonwealth will join 34 other states who also require name-based reporting. Name-based reporting allows for the most accurate tracking and will promote increased opportunities for disease intervention, and for funding.

Attempts to control the spread of HIV should not be entangled with politics. The Department's regulations will correct that, and allow epidemiologists to finally understand the extent of the spread of the infection in the Commonwealth. Name reporting allows for critical health practices, such as contact tracing, confirmation of treatment and assurance of services.

A unique identifier reporting system has failed in Texas, and is believed by the state medical society and the health officers of Maryland to be failing there as well. Codes within a unique identifier system require maintenance by providers of lists of names and codes, which increases the chances of breaches of confidentiality. A confidential name-based system is more secure and more confidential.

Response

The Department has not changed these regulations based on these comments. The Department is aware that the majority of the persons presenting testimony at the public meetings it held prior to proposed rulemaking were not in favor of name reporting. The Department did consider these comments in coming to its decision to propose confidential name reporting of the diseases, infections and conditions addressed in this rulemaking. The Department has carefully reviewed all known options for reporting HIV. After considering all of the information, concerns and recommendations that it received, as well as its own expertise and experience, the Department concluded that confidential name-based reporting is the best method for reporting HIV in the Commonwealth.

The Department disagrees that a unique identifier system would neither cause the Department to lose funding nor be less accurate than a system of reporting by name. A confidential name-based reporting system collects more accurate data since availability of the patient's name facilitates timely completeness of case reporting and allows the Department to review and eliminate duplicate case reports. If data is not timely, it is neither complete nor accurate for the Department's purposes. The data obtained under name-based reporting is more appropriate for the Department's needs. It fosters a more complete and accurate description of the epidemic for prevention and care planning, resource allocation, trend analysis and increased Federal funding; and Department facilitation of linkage to prevention and care services.

Further, the funding the Department obtains is better spent on prevention and treatment efforts than on developing a unique identifier reporting system. The confidential name-reporting system, which is already in place for other diseases, including AIDS, can provide accurate data at relatively small cost. Spending funds to develop a unique identifier based-reporting system is neither effective nor efficient in the fight to prevent and control the spread of HIV and AIDS.

A reporting system based on unique identifiers would be complex in comparison with the name-based systems currently in place, and would create problems for providers who are used to the current system of name-based reporting. This could lead to untimely reporting and underreporting, which, in turn, could lead to a loss in funding. Cases not

reported before a certain date during each grant period are lost to the Department for the purposes of funding.

The confidentiality and security of data kept in secure Department databases is greater than data maintained in the multiple lists linking names of cases to unique identifiers, which would most likely need to be developed and maintained at multiple provider sites to accomplish linkage of individuals with health care and other services, and to allow for follow-up. Therefore, name-based reporting is better able to meet the higher standards for confidentiality and security set by the CDC.

Name-based reporting will also be easier for providers and for public health agencies to use than a system based on unique identifiers. Reporters in the Commonwealth have used name-based reporting for AIDS and all other reportable diseases and conditions. While reporting by unique identifier would require the development of a new reporting system, and would require additional logs or other systems by which providers could cross check unique identifiers with names, name-based reporting will simply add additional diseases, infections or conditions to the current reporting system. Name-based reporting will eliminate the need for extensive training and the creation of separate databases to maintain logs of names, and will allow for complete reporting by the provider.

With respect to concerns that name-based reporting will deter persons from seeking testing and will delay treatment, there is no conclusive evidence to show that name

reporting does deter persons from seeking an HIV test. There is, however, growing evidence showing that name-based reporting can facilitate structured programs for linkage to care and prevention services. The Department will monitor the potential for deterrence of test seeking behavior on an ongoing basis using a CDC protocol that is available for HIV reporting states. Further, the Department will seek to ensure that anonymous testing is available throughout the Commonwealth for those persons who choose not to test under their own names.

The availability of anonymous HIV testing sites is more fully explained in the discussion of §27.32b (relating to confidential and anonymous testing). However, the Department commits to ensuring that anonymous HIV testing will be available to individuals in every county who choose to be tested anonymously, rather than confidentially.

Concerns that confidential name-based reporting will interfere with the physician-patient relationship, and the right to privacy, are addressed in the Department's responses to comments on § 27.32e (relating to record audits). Although the comments on that section were specifically directed to the Department's authority to "look back" at providers' records from the effective date of the regulations to January 1, 2000, the Department's response applies to these more general statements as well.

Concerns that information reported to the Department will be disclosed improperly and that discrimination will occur are without foundation based upon the Department's record. Several commentators have acknowledged that the Department's record on

confidentiality is "sterling." The Department agrees with the commentators who have stated that public perception and fear should not drive public policy. The Department understands concerns that information could be used to discriminate against individuals. The Department takes its responsibility not to release information reported to it very seriously.

There is a misperception among some persons that confidential name-based reporting is a threat to privacy and widespread discrimination will follow its implementation. The Department intends to combat this misperception by a public information campaign. The Department is exploring ways to reassure the public that HIV/AIDS reporting data are maintained under the highest security and confidentiality standards. There has never been a violation of privacy from the public health reporting system in this Commonwealth in 20 years of name-based AIDS reporting.

Finally, the Department currently meets, and will ensure that it continues to meet, CDC standards for security for reportable information.

Electronic reporting and security

Comment

Given the Department's record with HIV software systems in the area of HIV services, specifically Lifeplan, we question whether systems implementation will accurately track the data in question.

Response

The Department has not changed the regulations in response to this comment. The Bureau of Epidemiology has an excellent track record on the implementation of its surveillance responsibilities and use of software for tracking purposes. The Lifeplan system is a client-level data system used to report to the Department and then to the Health Resources and Services Administration (HRSA) data on client care services. The CDC -provided HARS software application is a proven, Nationally used tool. It is used to collect surveillance data.

Comment

We have used the HARS system with the Allegheny County Health Department, and we find it difficult to implement in a clinic setting. Data retrieval is difficult.

Response

The Department has not changed the regulations in response to this comment. HARS software is a surveillance application and is not intended to be used by providers for clinic management. The Department will prepare a subset of HARS to be used by providers so that reporting will be easier for them.

Comment

Even if electronic reporting simplifies the reporting process, there will be a need for additional computers to report remotely.

Response

The Department has not changed the regulations in response to this comment. The Department understands that additional computers may be necessary for some providers. The Department, however, believes that the simplification of the reporting process outweighs any minor cost incurred by individual providers.

Comment

The Department needs to ensure that reports can be submitted even if some of the information is not available.

Response

Reporters will be able to submit reports electronically, even if all the information is not provided. The Department will continue to follow-up on case reports of HIV with missing information, as it currently does for other diseases.

Comment

The Department should develop and communicate a plan regarding how it intends to provide software and training.

Response

The Department agrees with the comment, and will be working with representatives of stakeholders to both formulate and implement software delivery and training.

Comment

Not all providers may be able to submit reports electronically. The Department should develop a mechanism that will allow for submission of reports in another manner.

Response

The Department will work with those providers unable to submit reports electronically. The Department is prepared to accept a diskette by mail from those providers without internet service. The Department's general regulation on reporting (28 Pa. Code §27.4) allows for reporting incomplete information on cases by telephone although complete reporting will be required electronically through, for example, the use of diskettes, or through the use of a telephone number provided by the Department at no charge which would permit access to a web-based application to be used for reporting.

Comments

The regulations should specify security standards applicable to required electronic transmissions.

The regulations fail to describe the security systems that will be used to protect the medical information that will be transmitted electronically.

How will electronic reporting be done, and how will the Department assure the confidentiality and security of electronically reported information?

Response

Security of medical information and confidentiality of medical records and disease reports is a concern for both providers and the Department and local health departments. The Department is well aware of its responsibility to protect the confidentiality of the reports and information submitted to it. The security of electronic reporting will be accomplished through the use of encryption, and also the use of a digital certificate for each provider, which has, as part of its configuration, imbedded security similar to that used by banks for the electronic transfer of funds. This security, often referred to as PKI (Personal Key Identification), requires two keys to open files. One is held by the provider, the other by the Department. This same PKI process will be used for all electronic disease reporting to the Department. It is state-of-the-art technology.

Comment

The Department must include in its regulations a commitment to meet CDC data security standards.

Response

The Department has not changed the regulation in response to this comment. The Department already meets CDC security standards for HIV/AIDS case reports. As a condition of its CDC surveillance grant, the Department must meet these requirements, and adhere to them. As confirmed by the CDC, the Department is in compliance with these CDC requirements as of the last site visit from the CDC, which occurred in May of 2000. The county and municipal departments of health, which will act as local morbidity

report offices (LMROs), are also in compliance with these standards, as of the Department's latest audit of each department.

Comment

What equipment and software will providers be required to use, how much training will be required, and how often will it be offered? How much will this cost, and who will bear the cost, the Department or the reporters?

Response

The Department will provide the software to the provider free-of-charge. Instruction booklets or sheets will accompany the software. The Department will develop training schedules in consultation with stakeholder groups. The only cost to the provider will be transportation to the training site, and the cost of a computer with sufficient operating capacity and speed and an internet connection. It is expected that most providers will be able to use their existing computers for disease reporting. The Department is, however, prepared to accept diskettes by mail for those providers without internet service.

Confidentiality

Comments

How will these regulations affect previously tested persons already in care? How will they assure the confidentiality of their medical records?

Although the Department has had a positive record on confidentiality, the current regulations change the protections offered previously. Individuals who are HIV infected have faced discrimination once their HIV status has been learned.

If the Department goes forward with name reporting, measures to strengthen Statewide privacy protections for public health data must be examined immediately.

Response

The Department has not changed the regulations in response to these comments. Persons previously tested and in care will either be located through the Department's audit back to January 1, 2000, when additional testing is done to monitor the individual's status, or when the individual progresses from HIV to AIDS.

The Department has required the reporting of AIDS cases for roughly 20 years. The proven system for AIDS reporting has a 20-year track record of security and confidentiality, which includes stringent security and confidentiality features required by the CDC. The Department will protect the information reported on HIV in the same way, using the same CDC security standards, as they relate to HIV reporting. The security and confidentiality of the information will be maintained and, where necessary, improved in order to adequately handle the confidentiality of HIV case reports.

Comment

Since laboratories will now be required to transmit patient information, there is an increased risk for a breach of confidentiality. Although the ability to carry out this function is an integral part of laboratory services, the additional paper trails required by the newly mandated information sheets will challenge the ability to protect patient rights. The mere existence of special sheets attached to patient specimens may draw attention to the specimens, thus potentially violating patient confidentiality.

Response

Laboratories will be required to report results to the Department electronically. The patient information that will be sent to laboratories by providers is standard identifying information that is sent to laboratories in the normal course of business. The reason for including in the regulations language specifically requiring providers to submit this information to laboratories upon specimen submission is to ensure that this information is available for laboratories to send to the Department. This information is necessary in order to make the process of reviewing laboratory data for repeat case reports effective so that there is no need to contact providers about cases that have already been reported.

Laboratories will transmit this information to the Department electronically through secure data transmission portals. The system of electronic laboratory data transmission adopted by the Department is part of a National electronic laboratory reporting system being established by collaborating states and laboratories in conjunction with the CDC. The system meets the highest security and confidentiality standards for patient laboratory data transmission, as required by the CDC.

Comment

HIV reporting will not compromise confidentiality because appropriate safeguards currently exist. Reporting for other sexually transmitted diseases is required now, and we are not aware of any breach of confidentiality. National studies show that states with name reporting have not experienced any confidentiality problems.

Response

The Department agrees with the commentator.

Cost

Comments

It will take a good deal of time and resources to implement the regulations. The Department is requiring the reporting of all test results. Requiring duplicate reports seems costly. The regulations do not discuss the cost of this reporting, or how it will be funded. Providers with large numbers of patients will be adversely affected.

These regulations will have a major human and financial resources impact on high morbidity areas like Philadelphia. The Department does not say how it will financially support dual reporting.

The cost implications of the regulations are underestimated.

Our reporting system has been facilitated through cooperation with the Allegheny County Health Department, which performs on site data collection. Given the number of patients to whom we provide care, the information being required by these regulations will create an unmanageable workload for the clinic staff. Further, there is no provision for increasing staff in county health departments to collect this data.

Response

The Department does not believe the cost implications are underestimated, and has not changed the regulations in response to the comments. Further, these regulations are an addition to the existing list of over 50 reportable diseases, infections and conditions, and, for most reporters, additional infrastructure to accomplish this reporting should not be necessary.

The Department is sensitive, however, to provider concerns regarding funding. The Department has included in its budget funding to the local health departments, including Philadelphia County, for increased staff to handle additional workload. With respect to the comment relating to the large number of patients and clinic workload for private providers, current HIV cases will only need to be reported as they meet the AIDS case definition. The Department expects that will occur over an extended period of time and will not cause an undue burden. Further, county health departments will assist where that is possible. Electronic reporting by providers will limit any increased workload, since much of the information the Department is requiring will be collected for the patient's medical record, whether or not a reporting requirement exists.

With respect to the requirement that both laboratories and providers report the same case, the Department's reasons for requiring reporting by different types of reporters is discussed at greater length in responding to specific comments regarding multiple reporting and duplication of reports.

Comment

There will be an increased burden on research units and laboratories to implement reporting, including staff time and the cost of dedicated computer equipment and telephone lines for remote reporting.

Response

The Department has not changed the regulations in response to this comment. Dedicated computers and phone lines are not necessary, but password protection on provider databases is recommended. If the provider has an Internet Service Provider, the cost will be minimal.

Multiple reports

Comments

The Department should not require reporting of a case by more than one reporter.

The fiscal impact and purpose of the requirement of multiple reporters is not clear. Many persons may file reports on the same individual. What is the need for numerous reports

on a single case? What are the costs to the private sector when multiple reporters file and prepare reports? What will be the costs of effectively processing data from thousands of reporters in order to eliminate duplication?

Does the Department have a plan to figure out what to do when multiple reports are made of a single case?

Response

The Department currently requires the reporting by more than one type of reporter for every disease, infection and condition that is reportable under the law. This ensures that the Department will receive all the available material information relating to a case. The Department is concerned that if reporters "self-censor," based on their assumption that another person will make the report, there could be under-reporting. This would 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. It is better to get multiple reports providing the same information on a case, than to receive a single incomplete report.

With respect to the cost of reviewing several case reports to establish a single case file, that is a function which the Department currently performs for AIDS case reports. The Department has software that performs this function for it. There should be no additional

cost to the Commonwealth from filtering information from several case reports to develop a single comprehensive record.

Consent

Comment

Informed consent remains a hallmark of HIV testing protocols recommended by the CDC, and legislation relating to HIV testing. A system that allows individuals to bypass obtaining informed consent may undermine the trust and confidence between patients and their health care providers. Until the right of a patient to decline testing on a voluntary basis is revoked, the Department should not establish a system that may compromise this right.

Response

The Department has not changed the regulations in response to this comment. The regulations do not in any way prohibit or prevent a health care provider from obtaining consent from a patient before performing an HIV test. The Confidentiality of HIV-Related Information Act (35 P.S. §§7601-7612) (Act 148) still applies to the offering and provision of HIV testing, to the manner in which the results are given to the person tested, and to whether or not the information may be released to others. The regulations do not require an individual to take an HIV test of any kind, nor do they require an individual to take a test that will result in the name of the individual being reported to the Department. If a confidential test is chosen by the individual, the regulations require that the information establishing the presence of HIV be reported to the Department by the

individual's name. The regulations also require that the same results from an anonymous test be reported, although not by name. This is consistent with the requirements of Act 148.

Research exception

Comments

The regulations do not address problems that would arise for research programs if research programs are required to report the names of individuals who test positive for HIV infection or who have CD4 T-lymphocyte counts below a certain level. The regulations could alter a person's willingness to participate in a research project. The regulations should be modified to exclude research projects and research laboratories from reporting under an individual's name, data acquired for research purposes. This would not impact on the goal of reporting. Individuals participating in these studies would have been reported anonymously by their primary care provider or physician. Also, persons participating in these research projects already know their status, and, if they are positive, will be counseled to obtain medical care and will be provided information to facilitate their entry into the health care system.

Research studies use unique identifiers for all tests, and no demographic data is currently provided to diagnostic laboratories. Provision of such data to a laboratory is prohibited by informed consent documents signed by research subjects. Laboratories may be unable to accept additional information given terms of contracts and systems in place.

Research laboratories currently have no system in place to report communicable diseases. Data is generated solely for research protocols. All clinically relevant data is sent to the primary care provider after receiving written permission from the research subject.

Requiring that research facilities report HIV status will threaten their relationship with individuals who volunteer to participate in studies, and may result in an increase in HIV-infected individuals who are not receiving appropriate care.

New York has included a research exemption in its state statute.

Response

The Department has considered the comments recommending that research studies be exempted from reporting by name. The Department has decided against including such an exemption in the regulations. The Department has not provided for such exemptions for the reporting of other diseases, including AIDS. The Department does not believe that, at this time, there is sufficient evidence to show that the granting of such exemptions would further the public health purpose intended by these regulations. The Department, however, in determining whether such an exemption should be added at some future time, will consider any credible evidence research studies are able to provide to demonstrate that exempting research studies from name reporting from HIV will hamper the prevention and control of the spread of HIV. The Department understands that certain research studies begun prior to the effective date of these regulations may have been instituted under protocols that would prohibit the release of the information that the

Department is requiring. The Department will not require those studies to alter their protocols.

Section 27.1. Definitions.

This section includes definitions for Chapter 27. Three of the definitions proposed in the proposed rulemaking upon which this final rulemaking is predicated have already been adopted. They were adopted at Pa. B (January 26, 2002). Those terms were "district office," "local health department" and "local morbidity reporting office (LMRO)." Those terms and definitions, therefore, appear in the annex as existing regulation. A few commentators recommended changes to those definitions. The Department had either previously made the changes which were adopted in its final rulemaking on January 26, 2002, or has chosen not to revise the regulations. Those comments are discussed in greater detail below.

Comment

The Department should include the CDC case definition for AIDS in the regulations, rather than simply referring to it.

Response

The case definition for "AIDS" is the CDC definition. That definition is 15 pages long, and changes with new surveillance requirements or scientific needs. The Department has created a definition for "AIDS" in this section that incorporates by reference the CDC definition for "AIDS" published in its Morbidity and Mortality Weekly Report

(MMWR). This should enable persons to locate that definition if necessary. Historically, the CDC has revised the definition and published the revisions in the MMWR. Consequently, the Department has included with this definition a statement that it will publish references to the CDC MMWR updates to the case definition in the *Pennsylvania Bulletin* within 30 days of their publication.

The references for the current CDC case definitions are as follows:

> CDC. 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults. MMWR 1992;41 (RR-17).
>
> CDC. 1994 Revised Classification System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age. MMWR 1994;43 (RR-12).
>
> CDC. CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome. MMWR 1999;48 (RR-13).

Comment

The Department should expand the definition of "local morbidity reporting office (LMRO)" to minimize the potential for reporting to state health centers or other entities perceived to be county health departments. Inadvertent reporting to county offices might breach confidentiality, particularly in rural counties.

Response

The Department has not changed the definition in response to this comment. The definition of "LMRO" included in the regulations specifically identifies the district offices of the Department and the county/municipal health departments as LMROs. A list of these entities is available from the Department upon request, and the Department will publish a list in the *Pennsylvania Bulletin*. The Department does not agree that confusion will be likely to occur, especially since, with the exception of very few diseases, infections and conditions, all reporting is made to the LMROs.

Comment

The last sentence of the definition for "local health departments" referring to the Department maintaining a list, is substantive, and should be moved to the body of the regulations.

Response

The Department agrees with this comment. The sentence was deleted from the definition adopted on January 26, 2002.

Comments

To determine that a newborn has been exposed to HIV, as set forth in the definition for "perinatal exposure of a newborn to HIV," appears to require a subjective judgment by a broad array of persons. Substantive questions involving risk should not be included in a

definition. Reporters who are qualified to make the risk determination should be listed in the substantive part of the regulation.

Only information about newborns that come to term is useful in preventing a vertical transmission. Therefore, the definition should read as follows: "possible vertical transmission – potentially exposing a fetus to HIV during pregnancy of an HIV positive woman, regardless of the final serostatus of the infant."

Response

The Department has changed the definition to read: "The exposure of a newborn indicated by a positive HIV test result for the pregnant woman or mother of a newborn." The Department has made this change to clarify that, in determining whether a perinatal exposure has occurred, there is no determination of risk made. A newborn is considered exposed to HIV if the mother is HIV positive. The question of whether the child actually becomes HIV positive is a separate matter.

The Department has not changed the term defined to "potential vertical transmission." "Potential vertical transmission" is a term broader than "perinatal exposure." While "potential vertical transmission" applies to all types of mother-to-child transmission, "perinatal exposure" is limited to potential transmission in a perinatal setting. The Department has changed the definition to clarify that it is referring to potential perinatal transmissions by using the term "perinatal exposure."

The Department disagrees that only information regarding a newborn that has come to term is useful in preventing a vertical transmission,. The Department is requiring reporting of perinatal exposures, that is, potential perinatal transmissions. Information obtained on the status of the mother is instrumental in making prevention therapies available to the mother for the fetus.

Further, since some of these treatments are suspected of causing mutations in some children, reporting perinatal exposures will enable the Department to follow the women who tested positive and their children to collect data on this concern, and on the efficacy of other treatments. That information could provide data on whether, how, and why this occurs, and could lead to the development of safer treatment.

Comment

The Department should add definitions for the following terms: "unique identifier;" "confidential testing;" "anonymous testing;" and "State-designated anonymous testing sites."

Response

As has already been discussed, the Department has decided against the use of a unique identifier system in favor of a system of confidential name reporting. Therefore, the addition of a definition for the term "unique identifier" is not necessary.

The Department has added definitions of "anonymous HIV testing," "confidential HIV testing," and "State-designated anonymous HIV testing site" to eliminate confusion regarding anonymous and confidential testing, and the sites at which each or both may occur.

In anonymous HIV testing, an individual is informed that a fictitious name may be used to provide consent for the test. Although the individual is asked to provide information regarding age, sex, race, county, zip code, state of residence and the reason why the person believes that they are at risk for HIV, the individual may refuse to provide any of this information. Only an assigned number that is not linked to the person's identifying information identifies the person's written test result.

In confidential testing, the person signs a consent form with his or her name. Identifying information is collected and reported to the Department.

Anonymous HIV testing may only be conducted at a State-designated anonymous HIV-testing site. A State-designated anonymous HIV testing site is a testing site that has agreed to abide by the Department's guidelines for anonymous HIV testing, and that is supported by the Department, either through direct funding, or by having the laboratory tests paid for by the Department at the Department's contracted testing laboratory. Sites receiving other forms of public funding, for example, funding directly from the Federal government, or funding that does not require adherence to the Department's guidelines relating to anonymous testing, are not State-designated anonymous HIV-testing sites.

State-designated anonymous HIV-testing sites allow for the Department and local health departments to be linked to an HIV case quickly, without the patient's name, since that individual has already become part of the public health system by his choice of testing site. The difficulties which reporting by unique identifier would raise for public health staff in obtaining the timely information that would make involvement of the departments in the case useful, do not apply to an individual being tested anonymously in a forum linked to the Department or local health departments.

Section 27.2. Reportable diseases.

As proposed, this section would have added the diseases, infections and conditions addressed in these regulations to the general list of reportable diseases, infections and conditions in that section. The Department, at ___ Pa. B. ___ (January 26, 2002) removed that general list from §27.2. These regulations require no amendment to that section as it now reads. The addition to the list of diseases, infections and conditions required to be reported within the Commonwealth of the four reportable matters addressed in this rulemaking is accomplished by amending §§27.21a (relating to reporting of health care practitioners and facilities), 27.22 (relating to reporting by clinical laboratories) and 27.32a (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV).

Section 27.21a was not included in the proposed rulemaking relating to HIV reporting (31 Pa. B. 2126 (April 21, 2001)). It is a new regulation added by the January 26, 2002 amendments to Chapter 27. This rulemaking amends that section to accomplish what proposed revisions to §27.2 were intended to accomplish: the inclusion of general reporting requirements relating to HIV, certain CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV, and the clarification of reporting requirements relating to AIDS. More specific requirements for the reporting of those diseases, infections and conditions appear in new §27.32a.

Because the few comments received regarding proposed §27.2 apply to §§27.21a, 27.22 and 27.32a equally, those comments and these three sections will be discussed here.

Comments

Requiring reporting of low CD4 T-lymphocyte counts brings noninfected persons into the HIV/AIDS surveillance system. This could encourage inexperienced providers to use the CD4 T-lymphocyte test as a screening tool.

Requiring the reporting of low CD4 T-lymphocyte counts could cause the Department to contact parents of children with low CD4 T-lymphocyte counts and cause concern when the low count could be for a reason other than HIV or AIDS.

Reporting low CD4 T-lymphocyte counts, including results for persons who do not have HIV or AIDS, is burdensome for oncologists and other physicians who care for cancer

patients. It is unclear what the Department intends to do with this information, when it relates to cancer patients. Will it be referred to the Cancer Registry?

Response

The Department has not changed the regulations in response to these comments. CD4 T-lymphocyte counts of less than 200 cells/*u*L or of less than 14% of total lymphocytes, without other AIDS-defining illnesses, is an AIDS-defining condition in HIV positive persons. It is also an indication of severe immunosuppression that places the patient at risk for secondary infections. Low CD4 T-lymphocyte counts have a high "predictive value positive" and are mostly indicative of HIV/AIDS; more than 80% of low CD4 T-lymphocyte count test results are among HIV positive persons. Therefore, it is appropriate to require reporting of low CD4 T-lymphocyte counts. Reporting of low CD4 T-lymphocyte counts is now a standard component of HIV/AIDS reporting practices in many states that require CD4 T-lymphocyte tests to be reported.

The primary exception to this high predictive value is in specialized cancer treatment centers. Prevention of unnecessary reporting from such centers will be handled administratively by exempting specific facilities or clinics from reporting CD4 T-lymphocyte results based on documented results of audits indicating that that facility's yield of HIV/AIDS cases from CD4 T-lymphocyte results is low. In addition, it is the Department's public health responsibility to monitor trends of potential adverse public health outcomes from the population of vulnerable persons with severe immunosuppression regardless of HIV status. The Department will destroy reports of

low CD4 T-lymphocyte results that it determines do not coincide with the presence of HIV.

Further, the Department will not send to the Caner Registry information on cases reported because of the CD4 T-lymphocyte reporting requirement. The Cancer Registry is static. The Department does not undertake active cancer surveillance, nor does it track the impact of courses of treatment, as it does through HIV and AIDS reporting. Therefore, information relating to changing CD4 T-lymphocyte counts is not useful with respect to cancer cases.

Comment

All CD4 T-lymphocyte counts should be reportable, and not just those under 200 cells/*u*L or 14% of all T-lymphocytes.

Response

The Department has not changed the regulations in response to this comment. The Department has followed the CDC guidelines in the promulgation of the requirement that CD4 T-lymphocyte cell counts of equal to or less than 200, or 14% of total lymphocytes be reported. The Department is using CD4 T-lymphocyte counts as a marker for HIV disease counts over the limits the Department has included in the regulations would not be an accurate indicator for HIV. They could be indicative of too many other infections and conditions to be useful as an HIV marker.

Section 27.21. Reserved.

This section has also changed from proposed to final rulemaking based upon the January 26, 2002 amendments to Chapter 27. The Department proposed, in 31 Pa. B. 2126 to delete subsection (e), which required physicians to report cases of AIDS.

In the January 26, 2002 amendments to Chapter 27, however, the Department changed the title and substance of this section to deal solely with the reporting of AIDS by physicians and hospitals. The section had previously dealt with physician duties in reporting all reportable diseases. In this final rulemaking, the Department has consolidated all HIV and AIDS reporting requirements in §27.32(b) (relating to reporting AIDS, HIV, CD4-T lymphocyte counts and perinatal exposure of newborns to HIV). Therefore, the Department has repealed §27.21 in its entirety.

Section 27.22. Reporting of cases by clinical laboratories.

The amendments to this section require laboratories to report the diseases, infections and conditions included in this rulemaking in a particular manner. The amendments to the section also require electronic reporting by laboratories.

The April 21, 2001 proposed amendments to this section were made obsolete by the January 26, 2002 amendments. Consequently, Annex A shows the current amendments to this regulation as the regulation read after January 26, 2002. Subsection (a) is amended to add the types of testing information that is reportable. This is language that was deleted from the regulations in the January 26, 2002 amendments. The word

"examination" replaces the word "test," as a more accurate term. Subsection (b) is amended to require the reporting of HIV test results and low CD4 T-lymphocyte counts.

However, this section does not contain comprehensive standards for those reports. Those standards are provided in new §27.32a. For this reason, subsection (c) is amended to state that the reporting requirements of that subsection apply unless otherwise provided for in Chapter 27. Subsection (d) is amended to require that all laboratory results be reported to the Bureau of Epidemiology electronically in a manner specified by the Department, except for those diseases, infections and conditions which are contained in specific reporting requirements. These include HIV test results and CD4 T-lymphocyte test results.

Because part of the subject matter of proposed subsection (e) is deleted, and the remainder combined with subsection (d), the remaining subsections have been renumbered.

Since all of the comments received by the Department on this section were related to the proposed reporting requirements, the Department has chosen to discuss them under §27.32a, rather than here.

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

The Department has made a minor revision to this section to clarify that persons other than physicians and hospitals are not required to report cases of AIDS, and that only those individuals and entities required by §27.32a are required to report CD4 T-lymphocyte test results as defined by §27.21a, HIV test results or perinatal exposure of a newborn to HIV.

Section 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV.

This section identifies those types of persons and entities required to report the four diseases, infections and conditions included in this rulemaking, and specifies the manner by which the reporting is to be done. Section 27.32, which had been captioned "Reporting AIDS," was repealed by the January 26, 2002 amendments. The subject matter that had been addressed in that section, as expanded to include the three other reportable items added by these amendments, is now addressed in this section.

Subsection (a). Reporting by clinical laboratories.

The Department has moved the proposed language relating to reporting by laboratories of HIV test results and CD4 T-lymphocyte counts from proposed §27.22 (relating to reporting by clinical laboratories) to this subsection.

Comment

If a patient has more than one specimen sent to a laboratory for successive HIV tests, will the laboratory have to report each time the test was positive?

Response

A laboratory is required to report each time a test that establishes the presence of HIV is positive. A laboratory is not required to report preliminary tests for HIV that are not approved by the FDA as establishing the presence of HIV.

Comment

If a patient changes insurance, a new laboratory may have to report the patient. The multiple reports may create problems with confidentiality.

Response

Each test result that meets the standards in paragraphs (1) or (2) must be reported. The Department will review the test results, and develop a single case record, as it does with all other reportable diseases, infections and conditions. Rather than having reporters self-censor, leading to possible under-reporting, the Department prefers to follow the National standard for reporting, and require reporting by all reporters of all reportable results. If a report were not made, the Department would be unable to verify the case or respond appropriately. Confidentiality is not compromised by multiple reports of the same case. The steps that will be taken to safeguard confidentiality will be triggered by each report.

Comment

Requiring laboratories to report is burdensome and invasive of patients' privacy.

Response

The Department has not changed this regulation in response to this comment. This regulation has been developed to provide the Department with the most complete amount of relevant information available on a patient reportable under the regulation. This will help the Department identify every possible case of HIV, and act in a timely and effective manner when appropriate. To best ensure that a case is not missed, and that all important information is collected, the Department is requiring reporting from all possible reporters.

Further, the law directs the Department to require reporting for the protection of the public health. The General Assembly has already balanced the issue of total privacy of the individual against the public health and the health of the individual, and has determined that individual's complete privacy is subordinate to the Commonwealth's compelling need for protection of the public health through reporting of disease and condition information to the Department and the local health departments to facilitate epidemiological understanding and public health interventions. (See the Disease Prevention and Control Law of 1955 (35 P.S. §§521.1-521.21) (the act). The act prohibits the departments from releasing this information to any other person, except under very limited conditions.

Comment

Cases must be reported both to the State and to the local health departments. Both providers and laboratories are being required to report. The Department should either

require such dual reporting be done only for new, previously unreported cases, or must financially support the increased reporting requirements.

Response

Providers report only to LMROs; laboratories report only to the Department. The Department will provide the laboratory results to the LMROs electronically. The reasons for requiring multiple reports by multiple reporters have already been fully discussed. Further, the Department does not require repeated reports of a case by a provider who has previously reported the case. Each test that results in a CD4 T-lymphocyte count reportable under these regulations must be reported, however, regardless of whether the case has been previously reported, and will be used to assist the Department in evaluating the progression of disease.

Comment

The Department should include language in proposed §27.22 (c)(2) (adopted as §27.32(a)) exempting laboratories located within Philadelphia from reporting the names and addresses, including city, county and zip code, to the State Health Department. Laboratories would still be required to report this information to the Philadelphia Department of Health.

Response

The Department has not changed its regulations based on this comment. The Department has already discussed its reasons for adopting reporting by name, rather than by unique

identifier. The Department sees no reason to exempt laboratories within Philadelphia from this reporting requirement.

Comments

The Department should change the reference to name and address of the person from whom the specimen was obtained in proposed §27.22(c)(1) (adopted as §27.32a(a)(3)(i)) to the person's unique identifier.

The Department should change the reference to date of birth in proposed §27.22(c)(2)(iii) (adopted as §27.32(a)(3)(iii)) to year of birth.

Response

The Department has not changed this regulation in response to these comments. As has already been discussed, the Department has decided against the use of a unique identifier in favor of confidential name-based reporting.

Comment

The Department should delete proposed §27.22(c)(2)(ix), which would specifically require reporting of CD4 T-lymphocyte test results with a count of less than 200 cells/*u*L or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes. This subparagraph duplicates proposed §27.22(c)(2)(viii), which would require reporting of test results.

Response

The Department agrees, and has not included the substance of proposed §27.22(c)(2)(ix) in this section. Sections 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) identify the CD4 T-lymphocyte results that are reportable.

Comment

Does the requirement that reports be made to the Department within 5 days of obtaining the test results, found in proposed §27.22(d)(4) and (5) (adopted as §27.32a(a)(1) and (2)) afford a laboratory sufficient time to report?

Response

The Department has not changed the regulation in response to this comment. Five days affords a laboratory sufficient time to report. The Department's current experience with laboratory reporting for other reportable diseases, infections and conditions shows that laboratories are capable of reporting within this time frame.

Comment

The Department should delete the word "positive" from proposed §27.22(d)(5) (adopted as §27.32a(a)(2)) in proposed §27.2 (relating to reportable diseases) (now deleted) and in proposed §27.32a(a)(2) (adopted as §27.32a(b)(1)(ii)). Those regulations require reporting of "the positive results of any test approved by the FDA to establish the presence of HIV including serologic, virologic, nucleic acid (RNA or DNA) or any other

type of test . . . ." This should be changed because many of these tests provide neither a positive nor a negative, but rather provide points on a continuum. An example of this is a CD4 assay.

Response

The Department has not changed the regulations in response to this comment. The use of the word "positive" is appropriate as it relates to the definitions for each condition. If the test result meets the definition for a condition, the test result is "positive."

Subsection (b). ***Reporting by physicians, hospitals, persons or entities, who diagnose AIDS within the scope of their practice or who receive or provide HIV and CD4 T-lymphocyte test results.***

The proposed amendment of now repealed proposed §27.32 is adopted in subsection (b). Subsection (b) contains direction as to where, how and when reports are to be submitted by a physician, hospital, person providing HIV services or person in charge of an entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV or CD4 T-lymphocyte test results or provides HIV or CD4 T-lymphocyte test results to patients. Subsection (b) requires that reports made by the individuals and entities referenced in the subsection are to be made to the LMRO where the case was tested or has been diagnosed. The comments relating to proposed §27.32 are addressed under this subsection.

Comments

The Department should delineate who is required to report under this regulation. The section as proposed appears broad and vague. It does not appear to meet the intent of the

preamble, which stated that the Department intended to capture entities that do not have physicians, but receive test results. Nothing in this section excludes laboratories, and persons within laboratories could be covered by it. The fact that there is no definition of "HIV services" adds to the confusion.

This regulation should address to whom data is to be transmitted. The proposal suggests that it go to the county health departments, when in most counties it would be transmitted to the regional district office of the Department.

Response

The Department dose not agree that this subsection is overbroad or vague. The Department did intend to require reports from all entities that do not have physicians, but who receive or provide HIV and CD4 T-lymphocyte test results. This subsection only requires those entities and persons to file case reports if they also provide HIV services. The Department does agree, however, that a definition of "HIV services" would clarify this section further. The Department has added that definition to §27.1 (relating to definitions). The definition encompasses prevention, treatment and case management services, to ensure that the widest reporting is available to the Department. This definition eliminates a laboratory's duty to report from this subsection. Subsection (a), which is specifically directed to laboratories, does not make a laboratory subject to the requirement that it also provide HIV services. The substance of subsection (a) does not differ from what the Department proposed in §27.22(d).

With respect to the issue of where reports are to be made, the regulation clearly states that providers are to report to the LMRO where the case has been diagnosed or is located. An LMRO includes, by definition, the county and local health departments. There is no confusion about where laboratories are to report, since subsection (a) explains where, how and when laboratory reporting is to occur.

Comment

The regulations should specify who is responsible to report HIV for an entity that provides HIV services. Section 27.22 states that a person who is in charge of a laboratory is required to report. Similar language should be added here.

Response

The Department agrees, and has added to subsection (b)(1) "person in charge" language similar to that in §27.22.

Comment

Dentists should not have an HIV or AIDS reporting responsibility since a dentist does not diagnose or treat HIV or AIDS. The information that a dentist may have relating to HIV or AIDS is provided by a physician, a laboratory, or an infected patient.

Response

A dentist providing dental services to a client with HIV is no different than a dentist providing services to any other client with a communicable disease. A dentist operating in that capacity does not need to report HIV. Should the dentist have occasion to provide

HIV services, as defined in the regulations, and receive or provide HIV test results, that dentist would be required to report.

Comment

Proposed amendments to §27.32 (adopted as subsection (b) of this regulation) duplicate some of the reporting requirements in §§27.21 (relating to physicians who treat patients with reportable diseases including tuberculosis), 27.23 (relating to school reports of communicable diseases), 27.24 (relating to reports by heads of institution) and 27.25 (relating to reports by other licensed health practitioners). The Department should amend those existing sections of the regulations, rather than adopt a new regulation, to include new reporting requirements applicable to entties with reporting responsibilities subject to the aforementioned regulations.

Response

The Department has not changed the regulations in response to this comment. The Department repealed §§27.24 and 27.25 when it amended its regulations on January 26, 2002. At that time, it also amended §27.23. That section, which previously related to only school reports of communicable diseases, was amended to include reporting requirements for persons other than health care practitioners, facilities, laboratories or veterinarians. Because only certain persons are required to report HIV and AIDS, amending §27.23 to require HIV or AIDS reporting would not be appropriate. Further, the Department, in keeping with the January 26, 2002 amendments, has placed specific requirements relating to HIV and AIDS reporting in that part of Chapter 27 that includes

sections relating to diseases and conditions requiring special reporting. Section 27.21 is repealed by this rulemaking. The subject matter that had been addressed in §27.21 is now included in this subsection.

Comments

The Department's requirement that entities receiving test results report to the Department means that entities that receive test results are required to make diagnoses. Only clinicians should be required to make a diagnosis. Laboratories should not be required to report without a diagnosis.

The Department should clarify that only physicians can diagnose. As written, §27.32(a) (adopted as subsection (b) of this regulation) links hospital, person, or entity providing HIV services to the words "makes a diagnosis," and this causes confusion.

Response

The Department has not changed the regulation in response to these comments. The regulations do not require anyone to make a diagnosis of AIDS, nor do they require any practitioner to exceed the scope of the practitioner's practice. The regulations simply require that if a person makes a diagnosis of AIDS, that diagnosis must be reported. It is the Department's assumption that a person not authorized to diagnose within the scope of his practice will not do so. Further, the Department is not requiring entities or persons receiving the designated test results to make diagnoses, but is requiring them to report

those test results. Test results are empirical data. That data can be reported without the person making a clinical decision or diagnosis.

Comment

Requiring reporting of case management agencies is burdensome and invasive of a patient's privacy.

Response

The Department has not changed this regulation in response to this comment. This regulation has been developed to provide the Department with the fullest amount of relevant information available on a patient reportable under the regulation. This will help the Department identify every possible case of HIV, and act in a timely and effective manner when appropriate. To best ensure that a case is not missed, and that all important information is collected, the Department is requiring reporting from all possible reporters.

Further, the law directs the Department to require reporting for the protection of the public health. The General Assembly has already balanced the issue of total privacy of the individual against the public health and the health of the individual, and has determined that individual's complete privacy is subordinate to the Commonwealth's compelling need for protection of the public health through reporting of disease and condition information to the Department and the local health departments to facilitate epidemiological understanding and public health interventions. (See the Disease Prevention and Control Act of 1955 (35 P.S. §§521.1-521.21). The act prohibits the

departments from releasing this information to any other person, except under very limited conditions.

Comment

The Department should add the words "or is diagnosed within" to proposed §27.32 (a), following the words "when the individual who is a subject of the report is a resident."

Response

The commentator misunderstood the proposal. The Department had proposed to repeal §27.32(a) as it read at the time the proposals were made. The language referred to by the commentator is not included in §27.32a(b).

Comment

Proposed §27.32(a) (adopted as subsection (b)(1) of this section) would require that a report be made to the LMRO where the patient is diagnosed or tested. The Department is to be commended for including this language and changing its requirement that reports are to be made to the LMRO where the patient resides. The Department should make this change in all its disease regulations.

Response

The Department agrees that this should be the general reporting standard. In addition to retaining that language here, it has added similar language to its general regulations

relating to communicable and noncommunicable disease reporting in §27.4 (relating to reporting cases).

Comment

The Department should change the reference in proposed §27.32(a)(4) (adopted as subsection (b)(4)(iv) of this section) from "perinatal exposure" to "vertical transmission."

Response

The Department has not changed the regulation in response to this comment, for the reasons cited in its response to comments on the definition of "perinatal exposure of a newborn to HIV" in §27.1 (relating to definitions).

Comments

The Department should clarify what it means by "perinatal reporting." Will all newborns be tested? How will confidentiality be assured throughout the follow-up process?

There is a possibility of testing pregnant women. How will this be managed, and will confidentiality be ensured throughout any follow-up process?

Response

The Department has not changed the regulation in response to these comments. The Department is not requiring testing of newborns or pregnant women. The regulation requires a report of the exposure of the newborn to HIV. The Department has

recommended that pregnant women be tested, through dissemination of CDC guidelines for reducing perinatal exposure. The Department will work with the provider to ensure that the mother is properly counseled and has the opportunity to receive treatment that would reduce the risk of transmission. Again, the Department will only become involved with the case upon invitation by the provider, although the Department may contact a provider, advise of the services the Department can provide, and ask whether Department assistance is desired. The provider does not breach confidentiality or the patient-physician relationship by reporting in accordance with the regulations, since the reporting of patient information required by these regulations is a statutorily authorized exception to patient privacy.

Comment

Children exposed to HIV during pregnancy will be tracked by name, even if they are uninfected. There is no provision for removing from the database the names of those children who are shown not to be HIV-positive by a negative confirmatory test. This should be included in the regulations.

Response

The Department has not changed the regulation in response to this comment. Children who are not HIV-positive will not be a part of the HIV database. The names of children perinatally exposed to HIV will be maintained as part of the perinatal exposure database. The Department's retention of the names of children not found to be HIV-positive after birth is to allow the Department to perform follow-up for several reasons.

Requiring reporting of the perinatal exposure of newborns to HIV will 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 will 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.

Further, maintaining a list of children potentially exposed but not actually HIV positive will allow the Department to track certain treatments used in attempting to prevent the transmission of the infection, as has already been discussed.

Comment

The regulations should require a report of counseling given regarding treatment/prophylaxis, mode of prophylaxis chosen or denied and why, mode of delivery, and other indicators of efforts made to prevent vertical transmission. This would be useful in ensuring that best practices are in place and are utilized, when in the judgment of the woman, treatment is in her interest and those of the unborn child.

Response

The Department agrees that the question in the case report form that elicits information on prevention and care service referrals should be expanded. This will enable the Department to collect more useful information. The Department is taking steps to make that change to the form, but sees no need to revise subsection (b) to do so.

Comment

The Department should strike the language "in a timely manner" from §27.32(b) and replace it with a period of time consistent with the period of time in which other providers are required to report.

Response

The commentator misunderstood the proposal. The Department had proposed to repeal §27.32(b) as it read at the time the proposals were made. The language referred to by the commentator is not included in §27.32a(b).

Comments

The Department should remove references to the name of the individual from proposed §27.32(b) (adopted as subsection (b)(2)(i) of this section) and replace it with a unique identifier.

The Department should add language stating that Philadelphia County will substitute an identifier for the patient's name and street address as required in proposed §27.32(b)(1) (adopted as subsection (b)(2)(i) of this section) for reports of positive HIV test results.

Response

The Department has not changed the regulation in response to these comments. The Department has decided to use a system of name-reporting for the reasons previously discussed in this preamble. This reporting system will work the best for the Commonwealth if it is used throughout the Commonwealth.

Comment

Proposed §27.32(b)(8) and (9) duplicate the list of diseases in proposed §27.32(a) (adopted as subsection (b) of this section) and should be deleted.

Response

The Department has deleted the language, and replaced it with a requirement that the test results be reported. (See subsection (b)(2)(viii)).

Comments

The language "probable mode of transmission" in proposed §27.32(b)(10) (adopted as subsection (b)(2)(ix) of this section) requires a subjective assessment. This opens the door for judgments about the individual. Providers should be instructed to use only those categories of risk delineated by the CDC.

Rather than use the term "probable mode of transmission" the Department should use the exact language requesting the information used by the CDC report form on which the Department plans to collect this data.

Response

For purposes of clarification, the Department has changed the language. Subsection (b)(2)(ix) requires the patient's history on probable modes of transmission. The Department's reporting form is the CDC form, and the information the Department is soliciting are those categories of risk delineated by the CDC. Patient history information that is entered on the case report is essentially factual information elicited through patient interviews and counseling on the likely modes of transmission. This is documented in the patient chart or the counselor's notes and is not based on subjective judgments. As reported cases may often have multiple risks or exposures, the CDC data management software objectively assigns the patient's risk index for most likely/most probable mode of transmission using a hierarchical risk assignment algorithm based on a scientifically established hierarchy of relative risks for the various modes of transmission listed on the CDC report form. The phrase "patient history on probable modes of transmission" is therefore more descriptive of the information the Department intends to capture.

Comment

Unless the Department can specifically list what other information it would deem to be relevant, proposed §27.32(b)(14) (adopted as subsection (b)(2)(xiii) of this section) which

requires reporting of any other relevant information required by the Department, should be deleted.

Response

The Department has not changed the regulation in response to this comment. The Department and LMROs must be able to collect routine surveillance information and new scientific information made possible by developing technologies that could become relevant to tracking the progression of the epidemic, and to the Department's performance of its public health functions. For example, new research regimens could suggest that the Department collect information regarding the efficiency of those regimens on providers and patients. Inclusion of subsection (b)(2)(xiii) gives the Department the authority to revise the report form to solicit information that will be helpful for reasons not envisioned at this time.

Comment

The time line given for reporters to report in proposed §27.32(c) is too short, given the amount of information expected. This is especially true for physicians, unless the Department expects reporting to be done before the clients are given post-test counseling as required by law. This would mean reports would be required before patients could be notified personally.

Response

The Department has not changed the regulation in response to this comment. The Department is requiring in subsection (b)(1) that the report be made within 5 days after the person subject to subsection (b) makes the diagnosis or receives the test result. This provides ample time for the physician or counselor to discuss the matter with the patient. In any event, the Department will not be making any contact with a patient without a request from or referral by the provider. Therefore, the Department will have no contact with the patient unless the provider determines that contact would be useful for the patient. The only exception would be in the event of a public health emergency or outbreak, which would require that the Department act expeditiously to prevent and control the spread of disease, an unlikely scenario with respect to HIV or AIDS.

Comment

In proposed §27.32(c) (adopted as subsection (b)(3) of this section) the Department is requiring providers to maintain information in the patient's file. The Department should clarify what is meant by "the patient file." Is this to be electronic or on paper? Can the information be maintained in the disease report files, or must it be maintained in the patient's medical record?

Response

The Department has not changed the regulation in response to this comment. See subsection (b)(3). The Department intends the information to be maintained in the patient's medical record. The Department does not intend to specify the method by which that record is to be maintained.

Section 27.32b. Confidential and anonymous testing.

This section had been proposed as new §27.32a. It is being renumbered for the reason previously discussed. It permits anonymous testing at certain sites designated by the Department as anonymous HIV testing sites, and includes requirements for reporting by those sites. It also prohibits anonymous testing at any other site unless it is conducting blinded HIV testing authorized under section 5(f) of Act 148 (35 P.S. §7605(f)).

Several commentators supported the Department's intention to continue to allow anonymous testing sites within the Commonwealth, since anonymous HIV testing provides a testing option for those who would otherwise refuse to be tested.

Comments

The mechanisms for State designation of anonymous testing sites are unclear.

The Department should explain how anonymous testing sites are to be chosen. Planned Parenthood has worked tirelessly to build relationships with its clients. If the Department does not permit these sites to continue as anonymous testing sites, the Department will lose this data, since name-based reporting is likely to deter persons who would have been tested at these sites from being tested. The regulations should allow for sites currently providing anonymous testing to continue to do so.

In Bucks County, 5 Planned Parenthood sites and the county health department are the only sites at which anonymous testing are occurring. The hours at the county health department are inconvenient to young persons who work or are in school. The Department should make provisions in the regulations for sites currently providing anonymous testing to continue to do so.

The Department should ensure adequate numbers of anonymous testing sites. It is advisable to have one or more test sites per county.

The regulation does not define "State-designated," or indicate whether sites that are now providing anonymous testing will be "State-designated."

Response

To clarify the meaning and criteria applicable to anonymous and confidential testing, and State-designated HIV-testing sites, the Department has added definitions for these terms (see §27.1 (relating to definitions)), and has removed redundant language from this section. While the Department will not automatically accept any site currently performing anonymous HIV-testing as a State-designated site, all Department-supported HIV counseling and testing sites will remain State-designated anonymous HIV testing sites. A State-designated site must accept the Department's standards and guidelines for the provision of HIV testing and counseling. Anonymous HIV-testing sites may also provide confidential testing.

The number of anonymous test sites is over 130, located throughout the Commonwealth. These include the Department's state health centers, local health departments, and sites operated by publicly funded providers. This number fluctuates because of the constant addition and deletion of sites due to changes in these agencies and the turn-over of qualified counseling staff. The six county (Philadelphia, Allegheny, Bucks, Montgomery, Chester, and Erie) and four municipal (Allentown, Bethlehem, York, Wilkes-Barre) health departments were also asked by the Department to choose the number and location of sites to be designated as anonymous HIV-testing sites in each of their health jurisdictions. The Department did not limit the number of anonymous sites each of the county and municipal health departments were permitted to choose.

Further, the Department's regulations do not prohibit persons who operate State-designated anonymous HIV-testing sites from providing services in places where they have no physical facility. Once a site is designated by the Department, that site's operator can, and several do, send the site's workers into other communities where it has no physical facility to perform outreach and testing. The Department's regulations do not prohibit this type of outreach.

Comment

The number and distribution of anonymous HIV-testing sites may be inadequate, particularly in rural areas. The Department's regulations limit anonymous testing sites to those designated by the Department, limiting an already small number of sites. Although the Department has stated there are over 100 such testing sites, most of these sites offer

both confidential and anonymous testing. There are only 10 true anonymous testing sites available. Limiting anonymous testing sites will deter persons from being tested. The Department should make a commitment in the regulations to increase access to anonymous testing and expand the number of anonymous HIV-testing sites.

Response

It is not the intention of the Department to limit access to anonymous HIV testing. It is also not correct that there are only 10 true anonymous testing sites available. The Department has approximately 126 anonymous testing sites. The number of anonymous sites will fluctuate because of the constant additions and deletions of sites due to changes in contracted agencies and turnover of qualified counseling staff. All State-designated sites will provide anonymous testing if requested.

Comment

The regulations should require confidential testing sites to provide an explanation to the client that anonymous testing is available.

Response

While anonymous HIV-testing sites also provide confidential testing, the choice is up to the individual being tested. In the course of pre-test counseling at State-designated anonymous HIV-testing sites, the individual is advised that he may choose to be tested

confidentially or anonymously at that site. The Department supports other providers making persons aware of the possibilities of both anonymous and confidential testing, and referring them to anonymous HIV-testing sites, but will not require it. The Department is concerned that if a provider was required to offer anonymous testing to a a person coming to that provider for treatment or services other than HIV services, the provider could then find it necessary to refer the person to another site, and valuable treatment opportunities could be lost. For example, a person referred from an STD clinic to another site for anonymous HIV-testing might assume that the anonymous testing site could treat all his problems. He could fail to obtain necessary STD services, since those anonymous HIV-testing sites might not have the capability to treat STD.

Comment

The availability, location and hours of anonymous HIV-testing sites should be clearly established and publicized prior to the institution of these regulations.

Response

The regulations will be effective 90 days after publication. The Department will post lists of State-designated anonymous HIV-testing sites on its website, including the days and hours of operation of each during this 90-day period.

Comment

The regulations should make reference to periodic audits that will ensure anonymous testing is available to all Pennsylvania citizens throughout the Commonwealth.

Response

The Department has not changed the regulation in response to this comment. The Department will maintain quality control of the State-designated anonymous HIV testing sites in a manner that is consistent with the need to ensure the quality of patient care. The Department will also monitor the sites to ensure that anonymous HIV-testing is actually available at those sites.

Comment

Anonymous testing should not be permitted at only State-designated sites. Anonymous testing should be the standard procedure throughout the Commonwealth.

Response

The Department has already discussed its reasons for choosing to promote confidential name reporting as its primary mechanism for receiving HIV case reports.

Comment

The Department should add the following language:

> Anonymous testing for HIV in Philadelphia will be provided at those sites designated by the local health authority. Anonymous testing in Philadelphia is testing provided to an individual without collecting the name or any other information that could be used to ID an individual (street address, or algorithms based all or in part on the individual's name, social security number, date of birth). Confidential HIV testing in Philadelphia will require that the name of the individual tested be collected and reported to the local health authority upon receipt of reportable test results. Case reports on reportable HIV results obtained from all but anonymous test sites will be reported to the State substituting a UI for the name of the individual for whom a reportable HIV test result was obtained.

The Department should add the following language:

> Philadelphia will report anonymous HIV test results without identifiers, utilizing the case identification number to differentiate case reports.

Response

The Department has not changed the regulation in response to this comment. The Department has decided to use a system of name reporting for reasons previously

discussed in this preamble. This reporting system will work best for the Commonwealth if it is used throughout the Commonwealth.

Comment

The Department should delete the language from subsection (a) that states "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." The language is confusing, and seems to indicate that anonymous providers must report confidentially.

Response

The Department agrees that the section should be clarified, although it has not deleted the language in response to this comment. The Department has added, at the end of that sentence, the last sentence of subsection (a), the phrase "unless it is a State-designated anonymous HIV-testing site." This language reinforces the Department's requirement that only State-designated testing sites may perform anonymous testing.

Comments

The Department appears to be negating the intent of anonymous HIV testing by requiring the reporting of addresses and dates of birth. Unless two persons are twins and live together, this can hardly be considered to be anonymous HIV testing.

If anonymous testing sites report the information as the regulations require, how does the test remain anonymous? Does the Department intend to include certain categories of information from proposed §27.32? Why is this information, date of birth, address, sex, race, required in an anonymous test?

Response

The Department has revised subsection (b) to clarify that the Department is not requiring the reporting of addresses, social security numbers, and other potentially identifying data on individuals for whom an anonymous test was conducted. The data collected will be the information listed in §27.32a(b)(2), except for name and address, which is information useful for the public health purpose of assessing whether targeted high risk populations are being reached by counseling and testing. The Department has also changed the regulation to clarify that a preprinted number on the Department's HIV Counseling and Referral Form will be reported in lieu of the information required in §27.32a(b)(2)(i), with the exception of the individual's county of residence. An algorithm will not be used.

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

This section had been proposed as new §27.32b. It is being renumbered for the reason previously discussed. It states that counseling, testing, referral and partner notification must be done in accordance with Act 148. It also states that a person providing HIV test results to a patient may ask for the Department's assistance in doing so.

Comment

The language that states that persons may ask the Department's assistance if to do so would not violate Act 148 seems to suggest that the regulation supersedes the statute. This is not legally permissible.

Response

This section is included in the regulations so that the requirements of Act 148 would be considered by providers and acted upon. Act 148, however, provides that information may be released to the Department without consent as authorized by the act. Since the act gives the Department the authority to require reporting of HIV through the promulgation of regulations, as the Department has now done, information may be shared with the Department for purposes of post-test counseling without violating Act 148. Therefore, the language that states the Department's assistance may only be sought if Act 148 permits it is unnecessary, and the Department has deleted it.

Comments

The Department should clarify how follow-up of HIV infected persons will occur under a system of name reporting, and how confidentiality will be affected or improved. How will partner notification be handled?

We are concerned about how confidentiality will be protected during follow-up. We have had success in convincing the client to bring partners in when there is a diagnosis of

STD or a potential for HIV infection. Partner notification will be complicated by name-reporting.

Response

The Department currently performs partner notification or, as it is now referred to, partner counseling and referral services (PCRS), and has done so for some time. PCRS has two goals: first, to provide counseling and testing services to sex and needle sharing partners of HIV infected persons so they can avoid infection or, if they are already infected, to prevent transmission to others; and second, to help partners gain earlier access to HIV counseling, testing, medical evaluation, treatment and other prevention services. These could include, for example, STD treatment, drug treatment, violence prevention, social support, family planning and housing.

The agreement to participate in PCRS is voluntary on the part of the HIV infected person. In PCRS, the infected person is encouraged to voluntarily and confidentially disclose the identifying, locating and exposure information for each sex or needle-sharing partner that the Department or the infected person will attempt to inform. During PCRS, information about the infected person is never revealed to the partner; this includes the person's name, sex, and physical description, or time, type, or frequency of exposure the partner may have had with the infected person.

During HIV prevention counseling, the rationale and options for PCRS are explained by the counselor. The counselor assists the HIV infected person in understanding the

person's responsibility for ensuring the person's partners are informed of their possible exposure and for referring those partners to HIV prevention counseling, testing and other support services. The prevention counselor counsels the person on if, how and when specific partners should be informed of their risk of exposure. The options for PCRS are discussed and a plan for notifying each partner is developed. Options for PCRS include: client referral, in which the HIV infected person informs the person's partners and refers them to HIV counseling and testing services; provider referral, in which the provider informs the person's partners and provides the HIV counseling and testing; or dual or combined referral, in which both the infected person and the provider together inform the person's partners.

PCRS personnel never reveal to the individual's friends, relatives or neighbors why they are trying to find a person. They never leave a note or message that mentions HIV exposure as the reason for attempting to make contact. No information is revealed that might lead others to learn the reason for the attempted contact or that might otherwise lead to disclosure of sensitive information or to a breach of confidentiality. When the Department is involved in the partner notification process, all partners are informed of their possible exposure to HIV privately and face-to-face. If the partner refuses to meet with the provider, a telephone call might become necessary, but only limited information is provided to the partner over the phone, with the ultimate goal of arranging a face-to-face meeting.

Name reporting should not have an impact on this system. Partners must agree to be tested, and the fact that they choose to meet with a provider does not mean that testing occurs. Once the anonymous and confidential HIV testing options are explained to them, in the Department's experience, most partners opt for confidential HIV testing.

Section 27.32d. Department authority to require complete reporting.

This section had been proposed as new §37.32c, rather than §27.32c, as a result of a typographical error. It is being renumbered for the reason previously discussed. It reiterates the Department's authority, contained in the act, to make complete investigations of communicable and noncommunicable diseases, infections and conditions, including outbreaks. This includes the Department's authority to review records of reporters as necessary.

Comment

The section is unclear and should be broken into two sentences.

Response

The Department has made the change suggested.

Comment

Although the Department's need for the information is understood, the Department did not implement the HIV regulations in a timely fashion. The Department should work with physicians and hospitals to develop the most effective and least disruptive means of

collecting needed information. This same comment is applicable to §27.32e (relating to record audits.

Response

The Department is cognizant of the need for cooperation and education. The Department currently conducts case investigations involving physicians and hospitals, and always attempts to work with those entities to obtain their cooperation. The Department intends to continue that practice.

Comment

The Department should strike out "all other persons or entities providing HIV services" from this section, because only physicians or clinicians can make a diagnosis.

Response

As the Department has stated in its responses to comments on proposed §27.32(a) (adopted as 27.32a(b)), the regulations do not require any person to make a diagnosis. No person should be making a diagnosis other than a person who, within the scope of that person's practice, is authorized to do so.

Section 27.32e. Record audits.

This section had been proposed as new §27.32d. It is being renumbered for the reason previously discussed. It states that the Department will conduct record audits back to January 1, 2000, for the purposes of completing case investigations.

The Department has added the word "to" between the words "chapter" and "ensure" in subsection (b).

Comment

The Department should strike out "all other persons or entities providing HIV services" from subsection (a), because only physicians or clinicians can make a diagnosis.

Response

The Department has not changed the regulation in response to this comment. As the Department has stated in its responses to comments on proposed §27.32(a) (adopted as §27.32a(b)), the regulations do not require any person to make a diagnosis. As the Department has stated, it does not expect any person to make a diagnosis other than a person authorized to do so within the scope of that person's practice. If a diagnosis of AIDS is made, then it must be reported.

Comments

The Department should delete the proposed language stating that it will conduct audits back to January 1, 2000. This could create legal problems for providers, who do not have consents permitting them to release this information. If the individual is in care, he will have periodic tests, which, in the course of a year will cause him to be reported to the Department.

The proposed section violates the physician/patient privilege and ignores the need for patient consent.

Response

The Department has not changed the regulation in response to these comments. The audits will be done to collect information to complete HIV and CD4 T-lymphocyte case reports. The Department is instituting this requirement to allow 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 United States Department of Health and Human Services (HHS). One of the reasons the Department included this section, and §27.32d (relating to Department authority to require complete reporting), is that, in the past, the Department has had difficulty in securing cooperation from some providers. They have refused to allow the Department to review patient records to enable the Department to complete its case report files.

The Department's authority to conduct these record reviews without patient consent is clear in the act. Sections 3 and 5 of the act (35 P.S. §§521.3 and 521.5) 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 (35 P.S. §521.16) gives the Department, through the Board, the ability to promulgate whatever regulations are necessary to

prevent and control the spread of disease. Further, section 2102(a) of the Administrative Code of 1929 (71 P.S. §532(a)) gives the Department the authority to take the most efficient and practical means necessary for the prevention and suppression of disease. The reviews permitted by this section are necessary for locating cases of HIV and AIDS and controlling and preventing the spread of disease. Consequently, the Department is authorized by the act to promulgate regulations concerning those reviews, and is not required to obtain patient consent to conduct those reviews. The fact that the information is HIV-related information does not change this provision, since Act 148 includes an exception that allows the information to be provided to the departments for the purpose of disease control and prevention. (See 35 P.S. §7607(a)).

Further, since section 4 of the Act (35 P.S. §521.4) places reporting responsibilities on certain persons, and section 16(a) and (b) of the act (35 P.S. §521.16(a) and (b)) give 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. The regulation, therefore, clearly states the Department's authority to conduct these types of reviews of patient records. This should eliminate the occasional lack of cooperation on the part of providers.

Comment

The Department should not limit its ability or the ability of local health departments to obtain information by placing a time limitation on its back auditing. It should delete from subsection (a) the reference to January 1, 2000.

Response

In considering the interests of providers as well as the need for information, the Department has determined that reviewing information back to January 1, 2000, will sufficiently serve its purpose.

Comment

What are the "special reports" referenced by the Department in subsection (b)?

Response

By the term "special reports," the Department means reports that are not specifically disease reports, but, rather, are intended to help the Department prevent, track, and control the spread of disease in a particular situation, or that will enable the Department to monitor reporting practices. For example, several years ago, the Department received reports of needle stick injuries in a particular county, caused by adolescents surreptitiously sticking other persons with needles, and raising concern of potential exposures to blood borne diseases. The Department requested that the provider who initially made the report respond to a report form developed by the Department with regard to these specific incidents, including a time line and other questions relating to the potential exposures.

As another example, the Department could request that certain providers respond to a given set of ICD-9 codes with a listing of all cases matching those codes, and the dates, if

any, that the case was reported to the Department. This would enable the Department to determine if reporting by those specific providers was complete.

Several commentators made general comments that were not associated with any section or regulatory provision.

Comments

The effective date is unrealistic, given the publicity and training that needs to be accomplished.

It will be hard for reporters to be prepared to report by January 1, 2002. There will be limited staff available to implement these requirements. The Department should adjust implementation accordingly.

Response

The Department has changed the regulation. The Department had originally proposed a January 1, 2002 implementation date for reporting; however, the promulgation of these regulations was dependent upon the promulgation of final rulemaking relating to communicable and noncommunicable diseases. Those regulations were effective on January 26, 2002, therefore, the Department could not keep to the proposed implementation date. The implementation date for reporting will be 90 days after the effective date of these regulations. The Department's operational plan includes time for

training and education of providers. The Department is prepared to deal with issues that arise during that phase of the process.

Comment

The use of the term "public health intervention" in the preamble to the proposed regulations is neither defined nor described in regulatory language, and so is open to broad interpretation. Interventions should be specifically designed using best practice models and described in detail in regulatory language. These should only be implemented as a last resort after a clinician has exhausted all other avenues of contacting an individual, not as a first step as the regulations suggest. Community-based organizations should be included in these interventions.

Response

The Department has not changed the regulations in response to this comment. The term "public health intervention" does not appear in the regulations, and only appears in the preamble to proposed rulemaking in language discussing the Department's reasons for requiring the reporting of low CD4 T-lymphocyte counts that may ultimately prove not to be connected to HIV or AIDS. The Department has not included descriptions of "best practices" for public health interventions in the regulations. Public health practices change with changing science and the development of new and more effective methodologies for preventing and controlling the spread of disease. The Department will not tie itself to practices which might become outmoded. The Department consistently acts within CDC guidelines in carrying out its public health function.

With respect to the manner in which the Department will interact with private providers in the context of HIV cases, the Department has said that it will not directly contact the individual. The Department will use the provider as the point of contact, and will not intervene in the case without offering its services to the infected individual through the auspices of the provider.

Comment

The Department should add a penalty for those reporters who do not report in violation of the regulations. Allegheny County Health Department makes failure to report a summary offense and a civil penalty of up to $300.

Response

The Department has not changed the regulation in response to this comment. This rulemaking is a part of the Department's communicable disease regulations, and is being promulgated under the act. The act includes the same $300 penalty and summary offense referenced by the commentator for any violation of the act or regulations promulgated under the act. (35 P.S. §521.20). For the Department to impose an additional penalty would require action on the part of the General Assembly.

Comment

The discrepancy between this rulemaking and the rulemaking relating to communicable and noncommunicable diseases will make who is to report AIDS unclear.

Response

The Department has not changed the regulations in response to this comment. There will be no discrepancy in Chapter 27 of the Department's regulations regarding who is to report AIDS. The Department had proposed to delete language from its regulations requiring hospitals to report cases of AIDS. (See 30 Pa. B. 2715 (May 27, 2000)). That deletion was inadvertent. The Department addressed that issue in its final rulemaking published on January 26, 2002. As discussed previously in this preamble, the Department has taken steps to coordinate this rulemaking with the January 26, 2002 amendments to Chapter 27.

C. AFFECTED PERSONS

These regulations 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 are required to report diagnosed cases of AIDS, HIV test results, low CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV. The regulations also affect laboratories, which are required to report certain positive HIV test results and CD4 T-lymphocyte counts of a certain level.

The regulations 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 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. Unless these individuals choose to seek testing at an anonymous testing site (an option not available for pregnant women being tested during or immediately prior to labor because they are most likely in a hospital setting where anonymity is impossible) the names of those persons with these conditions or infected with HIV will be reported to the Department. The required reporting of these conditions and test results permits 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 enables 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 amendments 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 will 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 will be necessary because of the increase in the number of actual cases that should be reported once the reporting of the additional conditions imposed by this rulemaking goes into effect. The Department believes that this increase in cost to the Commonwealth will be outweighed by the savings from these regulations, caused by reporting of information that will enable the Department to focus prevention efforts on the most at-risk populations. Over time these activities will cause a reduction in the number of HIV cases in the Commonwealth. This will reduce health care costs.

No additional cost accrues 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 will 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 creates no measurable increase in paperwork. Cases of HIV, low CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV will 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, free of charge, to those persons required to report. The Department is willing to accept

alternative forms of electronic reporting from those who do not have internet access, for example, by accepting reporting by diskette.

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 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 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 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 disease prevention and control measures in those facilities.

F. EFFECTIVENESS/SUNSET DATES

The regulations will become effective upon final publication in the Pennsylvania Bulletin, however, the reporting requirements for positive HIV tests, low CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV will not become effective until 90 days after the final publication of this rulemaking. 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 of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§745.1-745.14), on December 8, 1999, the Department submitted a copy of Notice of Proposed Rulemaking published at 30 Pa. B. 2715 (May 27, 2000) to IRRC and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with section 5(c) of the Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

In compliance with section 5.1(a) of the Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on May 15, 2002. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed regulatory analysis form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

These final-form regulations were approved by the House Health and Human Services Committee on _____ and approved by the Senate Public Health and Human Services Committee on _____. IRRC met on _____ and approved the regulations in accordance with Section 5.1(e) of the Act. The Attorney General approved the regulations on _____.

H. CONTACT PERSON

Questions regarding these regulations may be submitted to Joel H. Hersh, Director, Bureau of Epidemiology, Department of Health, P.O. Box 90, Harrisburg, PA 17108, (717) 783-4677. Persons with disabilities may submit questions in alternative formats such as audio tape, Braille or 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 at the above address or telephone numbers so that necessary arrangements may be made.

I. FINDINGS

The Department, with the approval of the Board, finds that:

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

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

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

J. ORDER

The Department, with the approval of the Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 28 Pa. Code Chapter 27, are hereby amended by repealing §27.21, by amending §§27.1, 27.21a, 27.22, and 27.23, adding §§27.32a, 27.32b, 27.32c, 27.32d and 27.32e, as set forth in Annex A.

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

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

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

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

ANNEX A

TITLE 28. HEALTH AND SAFETY

* * *

PART III. PREVENTION OF DISEASES

* * *

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

§27.1. Definitions.

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

* * *

AIDS (ACQUIRED IMMUNE DEFICIENCY SYNDROME) – AS DEFINED BY THE CDC CASE DEFINITION PUBLISHED IN THE CDC MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR). (THE DEPARTMENT WILL PUBLISH IN THE *PENNSYLVANIA BULLETIN* A REFERENCE TO A CDC UPDATE OF THE CASE DEFINITION WITHIN 30 DAYS OF ITS PUBLICATION IN THE MMWR).

ANONYMOUS HIV TESTING – HIV TESTING PERFORMED AT A STATE-DESIGNATED HIV TESTING SITE FOR AN INDIVIDUAL WHO CHOOSES NOT TO PROVIDE HIS NAME IN GIVING CONSENT FOR THE TESTING.

CDC – Centers for Disease Control and Prevention.

* * *

CONFIDENTIAL HIV TESTING. HIV TESTING PERFORMED FOR AN INDIVIDUAL WHO, IN GIVING HIS CONSENT FOR THE TESTING, PROVIDES HIS NAME AND OTHER PERSONAL OR DEMOGRAPHIC IDENTIFIERS.

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

* * *

FDA – Food and Drug Administration.

* * *

HIV SERVICES – THE RANGE OF SERVICES, INCLUDING PREVENTION, COUNSELING, TESTING, TREATMENT, CASE MANAGEMENT, SUPPORT AND REFERRAL SERVICES, WHICH ARE PROVIDED TO PERSONS INFECTED WITH OR AFFECTED BY HIV OR AIDS, AND ARE INTENDED TO ALLEVIATE PHYSICAL AND PSYCHOSOCIAL PROBLEMS CREATED BY THESE DISEASES AND CONDITIONS.

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).

* * *

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~~ THE POTENTIAL PERINATAL TRANSMISSION OF HIV TO A NEWBORN INDICATED BY A POSITIVE HIV TEST RESULT FOR THE PREGNANT WOMAN OR MOTHER OF A NEWBORN.

* * *

STATE-DESIGNATED ANONYMOUS HIV TESTING SITE -- AN HIV TESTING SITE SUPPORTED BY THE DEPARTMENT EITHER THROUGH DIRECT FUNDING OR PAYMENT FOR TESTING, WHICH PROVIDES ANONYMOUS AND CONFIDENTIAL TESTING AND WHICH AGREES TO ADHERE TO COUNSELING AND TESTING STANDARDS AND GUIDELINES ISSUED BY THE DEPARTMENT.

* * *

SUBCHAPTER B. REPORTING OF DISEASES

§27.21. ~~Reporting of AIDS cases by physicians and hospitals~~ (RESERVED).

~~A physician or a hospital is required to report a case of AIDS within 5 work days after it is identified to the local health department if the case resides within the jurisdiction of that local health department. In all other cases, the physician or hospital shall report the case to the HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.~~

§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:

* * *

(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.

* * *

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 (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

HIV (HUMAN IMMUNODEFICIENCY VIRUS) (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

PERINATAL EXPOSURE OF A NEWBORN TO HIV (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

§27.22. **Reporting of cases by clinical laboratories.**

(a) A person who is in charge of a clinical laboratory in which a laboratory ~~examination~~ 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 ~~examination~~ 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/*UL* OR LESS THAN 14% OF TOTAL LYMPHOCYTES (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

HIV (HUMAN IMMUNODEFICIENCY VIRUS) (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

(c) ~~The~~ UNLESS OTHERWISE PROVIDED FOR IN THIS CHAPTER, THE report shall include the following:

(1) The name, age, address, and telephone number of the person from whom the specimen was obtained.

(2) The date the specimen was collected.

(3) The source of the specimen (such as, serum, stool, CSF, wound).

(4) The name of the test or examination performed and the date it was performed.

(5) The results of the test.

(6) The range of normal values for the specific test performed.

(7) The name, address, and telephone number of the physician for whom the examination or test was performed.

(8) Other information requested in case reports or formats specified by the Department.

(d) ~~The report shall be submitted~~ LABORATORY TEST RESULTS SHALL BE REPORTED by the person in charge of a laboratory ~~in either a hard copy format or an electronic transmission format specified by the Department.~~ DIRECTLY TO THE DEPARTMENT'S BUREAU OF EPIDEMIOLOGY THROUGH SECURE ELECTRONIC MECHANISMS IN A MANNER SPECIFIED BY THE DEPARTMENT, EXCEPT FOR THE FOLLOWING:

~~(e) Reports made on paper shall be made to the LMRO where the case is diagnosed or identified. Reports made electronically shall be submitted to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology~~. Reports of maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell hemoglobinopathies, cancer, CD4 T-LYMPHOCYTE TEST RESULTS WITH A COUNT OF LESS THAN 200 CELLS/UL OR LESS THAN 14% OF TOTAL LYMPHOCYTES, HIV (HUMAN IMMUNODEFICIENCY VIRUS), and lead poisoning shall be ~~reported~~ MADE IN THE MANNER AND to the location specifically designated in this subchapter. See §§27.30, 27.31, 27.32A

and 27.34 (relating to reporting cases of certain diseases in the newborn child; reporting cases of cancer, REPORTING AIDS, HIV, CD4 T-LYMPHOCYTE COUNTS, AND PERINATAL EXPOSURE OF NEWBORNS TO HIV and reporting cases of lead poisoning).

~~(f)~~(E) A clinical laboratory shall submit isolates of salmonella and shigella to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

~~(g)~~(F) A clinical laboratory shall submit isolates of Neisseria meningitidis obtained from a normally sterile site to the Department's Bureau of Laboratories for serogrouping within 5 work days of isolation.

~~(h)~~(G) A clinical laboratory shall send isolates of enterohemorrhagic E. coli to the Department's Bureau of Laboratories for appropriate further testing within 5 work days of isolation.

~~(i)~~(H) A clinical laboratory shall send isolates of Haemophilus influenzae obtained from a normally sterile site to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

~~(j)~~(I) The Department, upon publication of a notice in the *Pennsylvania Bulletin*, may authorize changes in the requirements for submission of isolates based upon medical or public health developments when such departure is determined by the Department to be necessary to protect the health of the people of this Commonwealth. The change will not remain in effect for more than 90 days after publication unless the Board acts to affirm the change within that 90-day period.

* * *

§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/*U*L OR LESS THAN 14% OF TOTAL LYMPHOCYTES, HIV TEST RESULTS OR PERINATAL EXPOSURE OF A NEWBORN TO HIV, 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):

* * *

§27.32A. REPORTING AIDS, HIV, CD4 T-LYMPHOCYTE COUNTS, 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 ELECTRONICALLY TO THE HIV/AIDS EPIDEMIOLOGY SECTION, DIVISION OF INFECTIOUS DISEASE EPIDEMIOLOGY, BUREAU OF EPIDEMIOLOGY, WITHIN 5 DAYS OF OBTAINING THE TEST RESULTS.

(2) A PERSON IN CHARGE OF A CLINICAL LABORATORY SHALL REPORT POSITIVE TEST RESULTS OFANY 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, WITHIN 5 DAYS OF OBTAINING THE TEST RESULTS.

(3) 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.

(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) THE NAME OF THE PERSON OR ENTITY SUBMITTING THE SPECIMEN FOR TESTING.

(X) THE ADDRESS OF THE PERSON OR ENTITY SUBMITTING THE SPECIMEN FOR TESTING, INCLUDING THE ZIP CODE, PHYSICAL ADDRESS AND TELEPHONE NUMBER OF THE SUBMITTER.

(4) 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 (A)(3), WITH THE EXCEPTION OF SUBPARAGRAPHS (VI) THROUGH (IX). IN ADDITION TO THE INFORMATION INCLUDED IN SUBSECTION (A)(3), 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.

(B) REPORTING BY PHYSICIANS, HOSPITALS, PERSONS OR ENTITIES, WHO DIAGONOSE AIDS OR WHO RECEIVE OR PROVIDE HIV AND CD4 T-LYMPHOCYTE TEST RESULTS.

(1) A PHYSICIAN, HOSPITAL, PERSON PROVIDING HIV SERVICES OR PERSON IN CHARGE OF AN ENTITY PROVIDING HIV SERVICES, WHO MAKES A DIAGNOSIS OF AIDS OR WHO RECEIVES HIV OR 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 WITHIN 5 BUSINESS 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 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

(III) A CD4 T-LYMPHOCYTE TEST RESULT WITH A COUNT OF LESS THAN 200 CELLS/*UL* OR A CD4 T- LYMPHOCYTE PERCENTAGE OF LESS THAN 14% OF TOTAL LYMPHOCYTES (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

(IV) A PERINATAL EXPOSURE OF A NEWBORN TO HIV (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

(2) 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:

(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.

(III) THE INDIVIDUAL'S DATE OF BIRTH.

(IV) THE INDIVIDUAL'S SEX.

(V) THE INDIVIDUAL'S RACE OR ETHNICITY.

(VI) THE DATE OF EACH TEST PERFORMED.

(VII) THE TYPE OF TEST OR TESTS PERFORMED.

(VIII) THE TEST RESULTS.

(IX) THE PATIENT'S HISTORY ON PROBABLE MODES OF TRANSMISSION.

(X) THE TREATMENT PROVIDED.

(XI) 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.

(XII) 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.

(XIII) ANY OTHER INFORMATION THE DEPARTMENT DETERMINES TO BE RELEVANT.

(3) IN ADDITION TO REPORTING THE AIDS DIAGNOSIS OR THE RECEIPT OF TEST RESULTS, THE REPORTER SHALL MAINTAIN THE DATA REQUIRED IN PARAGRAPH (2) IN THE PATIENT FILE ON THE DEPARTMENT'S HIV/AIDS REPORT FORM.

(4) 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 PARAGRAPH (2) ELECTRONICALLY TO THE DEPARTMENT'S BUREAU OF EPIDEMIOLOGY THROUGH A SECURE ELECTRONIC MECHANISM SPECIFIED BY THE DEPARTMENT.

~~§27.32a~~ §27.32B. Confidential and anonymous testing.

(a) Anonymous testing for HIV, except for blinded HIV testing authorized under section 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. A person or entity 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, UNLESS IT IS A STATE-DESIGNATED ANONYMOUS HIV-TESTING SITE.

(b) Anonymous test results shall be reported in accordance with ~~§27.32~~ §27.32A(B)(2) (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~~ . IN LIEU OF THE INFORMATION REQUIRED IN §27.32A(B)(2)(I), THE REPORT OF AN ANONYMOUS TEST SHALL INCLUDE an ~~anonymous code assigned at the time the specimen is collected in accordance with a Department approved anonymous test site algorithm~~ ASSIGNED NUMBER PREPRINTED ON THE HIV COUNSELING AND TESTING REPORT FORM. THE REPORT SHALL ALSO INCLUDE THE INDIVIDUAL'S COUNTY OF RESIDENCE.

~~§27.32b~~§27.32C. 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~~§27.32D. Department authority to require complete reporting.

~~To~~ THE DEPARTMENT WILL HAVE ACCESS TO AND MAY REVIEW THE PATIENT RECORDS OF PHYSICIANS, HOSPITALS, PERSONS PROVIDING HIV SERVICES AND PERSONS IN CHARGE OF ENTITIES PROVIDING HIV SERVICES, WHO MAKE DIAGNOSES OF AIDS, OR WHO RECEIVE OR PROVIDE HIV AND CD4 T-LYMPHOCYTE 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 ~~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~~ §27.32E. Record audits.

(a) The Department may conduct record audits of the records of physicians, hospitals, ~~and other~~ 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 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 TO ensure compliance with this chapter.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

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

May 15, 2002

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health Final Regulation No. 10-166
Reporting of HIV test results, CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV

Dear Mr. Nyce:

Enclosed is a copy of final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). Section 5.1(a) of the Act provides that, upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the Standing Committees, a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. Their comments, which discussed a number of provisions contained in the proposed regulations, were forwarded to the Commission upon receipt by the Department.

Section 5.1(e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Deborah Griffiths, Director, Office of Legislative Affairs.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

List of Commentators

Barry Busch
840 Upland Avenue
Upland, PA 19015

Joan Boerner
Cedarbrook Nursing Home
350 South Cedarbrook Road
Allentown, PA 18104

Niles Schore
Room 543 Main Capitol Building
Harrisburg, PA 17120

Tyrone Burke
1242 Snyder Avenue
Second Floor
Philadelphia, PA 19148

Anthony Harris
P.O. Box 9169
Philadelphia, PA 19139

Jeannine Scott-Barber
2403 Ingersoll Street
Philadelphia, PA 19121

Martin W. Scott
902 South 49th Street
Number 2
Philadelphia, PA 19143

Tangela Logan
1230 West. Allegheny Avenue
Philadelphia, PA 19133

Charles Duncan
3114 Custer Street
Philadelphia, PA 19134

Eddie Davis
Philadelphia Fight
1233 Locust Street
Philadelphia, PA 19107

Gwendolyn Brown
333 West Upsah Street
Philadelphia, PA 19119

Andrew J. O'Connor
4144 West Girard Avenue
Philadelphia, PA 19104

Renee Carter and Thea Ellis
2540 South Beulah Street
Philadelphia, PA 19148

Arthur Smith
208 Ashby Road
Number 2
Upper Darby, PA 19082

Scott Evans
1242 Snyder Avenue
Second Floor
Philadelphia, PA 19148

F. Steven Robinson
1220 Lindley Avenue
Number 208
Philadelphia, PA 19141

Robert A. McLean
2749 N13th Street
Philadelphia, PA 19133

Joe D'Marco
7041 Upper York Road
New Hope, PA 18938

Charles R. Hunter
1624 West Ruscomb Street
Philadelphia, PA 19144

Mark Allen Machlin
3865 Frankford Avenue
Apartment 1F
Philadelphia, PA 19124

Marvin Crawford
218 Ithen Street
Philadelphia, PA 19139

Joan Elsasser
907 South 48th Street
Philadelphia, PA 19143

Timothy Walker
3912 N. Pulaski Avenue
Philadelphia, PA 19140-3402

Robert Moellmann
4952 Catharine Street
Philadelphia, PA 19143

Richard Baron
1530 Locust PMB 239
Philadelphia, PA 19102

Carolyn Smaller
2633 Roberts Avenue
Philadelphia, PA 19129

Tara Dwyer
1622 Fitzwater Street
Philadelphia, PA 19146

Michael Slover
2441 Kensington Avenue
Philadelphia, PA 19125

Robert William Rivera II
759 South 8th Street
Apartment 2
Philadelphia, PA 19147

Gloria Prusakowski
712 South 19th Street
Apartment 3
Philadelphia, PA 19146-1802

Mrs. Ann Williams
4211 Sydenham Street
Philadelphia, PA 19140

Allen Hailef
8623 Forrest Avenue
Philadelphia, PA 19150

Robert T. O'Brien
907 South 48th Street
Philadelphia, PA 19143

Joseph Cannon
3865 Frankford Avenue
Philadelphia, PA 19124

Melvin White
6424 Keystone Street
Apartment B1
Philadelphia, PA 19135

William Cooper
5225 Master Street
Philadelphia, PA 19131

Jennifer Przewosnik
1622 Fitzwater Street
Apartment 2
Philadelphia, PA 19146

John H. Beel
4953 Catherine Street
Philadelphia, PA 19143

Doyin Desalu
Southwestern PA AIDS Planning Coalition
907 West Street
Fifth Floor
Pittsburgh, PA 15221-2841

Berks AIDS Network
429 Walnut Street
P.O. Box 8626
Reading, PA 19603-8626

Judith Natale Sabino
Community Health & Health Studies
P.O. Box 7017
Allentown, PA 18105-7017

Paula A. Bussard
The Hospital & Healthsystem of PA
4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600

Bruce W. Flannery
Pennsylvania Coalition of AIDS
Service Organizations
624 West Lincoln Highway
Exton, PA 19341

Larry Frankel
American Civil Liberties Union
125 South 9th Street
P.O. Box 1161
Philadelphia, PA 19105-1161

F.T. Wright
Tyson 321 Willings Alley
Philadelphia, PA 19106

Mark Keith
321 Willings Alley
Philadelphia, PA 19106

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 10-166

SUBJECT: Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV

AGENCY: Department of Health

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

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

2002 MAY 15 PM 3:15

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
5/15	N. Thompson	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
	M. McKinney	
5-15-02	Debbie K. Eaton	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
5/15	L Caler	
5/15	D. Nagel	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

May 1, 2002

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH
(717) 783-2500

May 31, 2002

Robert E. Nyce
Executive Director
Independent Regulatory Review Committee
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: Regulation #10-166 (IRRC #2185)
Department of Health
Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV

Dear Mr. Nyce:

We have reviewed your letter of May 31, 2002 recommending that the Department consider tolling the review period for Regulation #10-166 (IRRC #2185) in order to made certain revisions. We have reviewed the recommended revisions and would like to toll the review period in order to make the revisions discussed below.

1. The Department will delete Section 27.32a(b)(2)(xiii) which requires reporters to provide "any other information the Department determines to be relevant" since this section does delineate the type of information required to be reported.

2. The Department will change Section 27.32a(a)(1) to reflect that reports of CD4 T-lymphocyte test results will be made in accordance with the requirements of Section 27.22 (b). The purpose for this revision is to clarify that not all CD4 T-lymphocyte test results are required to be reported. Only 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 will be required to be reported.

3. The Department will delete the phrase "unless otherwise provided for in this chapter" in Section 27.22(c) and replace it with "except as provided for in subsection (d).

4. The Department will add a new Section 27.32b(c) in order to further clarify how the Department will create and fund additional State-designated anonymous HIV testing sites. (See recommended language on page 11 attached).

We have attached the pages of the regulations reflecting these changes.

We appreciate your consideration in this matter and remain available to answer any questions you may have.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

cc. Honorable George T. Kenney, Jr., Majority Chairman, House Health and Human Services Committee
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee
Honorable Harold F. Mowery, Jr., Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee

PREAMBLE – PAGE 37

The Department has added definitions of "anonymous HIV testing," "confidential HIV testing," and "State-designated anonymous HIV testing site" to eliminate confusion regarding anonymous and confidential testing, and the sites at which each or both may occur.

In anonymous HIV testing, an individual is informed that a fictitious name may be used to provide consent for the test. Although the individual is asked to provide information regarding age, sex, race, county, zip code, state of residence and the reason why the person believes that they are at risk for HIV, the individual may refuse to provide any of this information. Only an assigned number that is not linked to the person's identifying information identifies the person's written test result.

In confidential testing, the person signs a consent form with his or her name. Identifying information is collected and reported to the Department.

Anonymous HIV testing may only be conducted at a State-designated anonymous HIV-testing site. A State-designated anonymous HIV testing site is a testing site that has agreed to abide by the Department's guidelines for HIV testing, which are based on the CDC's guidelines, and that is supported by the Department, either through direct funding, or by having the laboratory tests paid for by the Department at the Department's contracted testing laboratory. Sites receiving other forms of public funding, for example, funding directly from the Federal government, or funding that does not require adherence

PREAMBLE – PAGE 44

The Department has made a minor revision to this section to clarify that persons other than physicians and hospitals are not required to report cases of AIDS, and that only those individuals and entities required by §27.32a are required to report CD4 T-lymphocyte test results as defined by §27.21a, HIV test results or perinatal exposure of a newborn to HIV.

Section 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV.

This section identifies those types of persons and entities required to report the four diseases, infections and conditions included in this rulemaking, and specifies the manner by which the reporting is to be done. Section 27.32, which had been captioned "Reporting AIDS," was repealed by the January 26, 2002 amendments. The subject matter that had been addressed in that section, as expanded to include the three other reportable items added by these amendments, is now addressed in this section.

Subsection (a). *Reporting by clinical laboratories.*

The Department has moved the proposed language relating to reporting by laboratories of HIV test results and CD4 T-lymphocyte counts from proposed §27.22 (relating to reporting by clinical laboratories) to this subsection. The Department has added a reference to section 27.22(b) (relating to reporting of cases by clinical laboratories) to subsection (a) to clarify that laboratories are not required to report all CD4 T-lymphocite case results, but only those that meet the definition included in section 27.22(b).

CDC report form. The phrase "patient history on probable modes of transmission" is therefore more descriptive of the information the Department intends to capture.

Comment

Unless the Department can specifically list what other information it would deem to be relevant, proposed §27.32(b)(14) (included as subsection (b)(2)(xiii) of this section) which requires reporting of any other relevant information required by the Department, should be deleted.

Response

The ~~Department has not changed the regulation in response to this comment. The Department and LMROs must be able to collect routine surveillance information and new scientific information made possible by developing technologies that could become relevant to tracking the progression of the epidemic, and to the Department's performance of its public health functions. For example, new research regimens could suggest that the Department collect information regarding the efficiency of those regimens on providers and patients. Inclusion of subsection (b)(2)(xiii) gives the Department the authority to revise the report form to solicit information that will be helpful for reasons not envisioned at this time.~~ Department agrees with the comment, and has deleted subsection (b)(2)(xiii).

(see §27.1 (relating to definitions)), and has removed redundant language from this section. While the Department will not automatically accept any site currently performing anonymous HIV-testing as a State-designated site, all Department-supported HIV counseling and testing sites will remain State-designated anonymous HIV testing sites. In addition, the Department may choose to designate and fund additional anonymous HIV-testing sites if the Department finds, based on information reported to it under the Communicable Disease Regulations, that individuals are having problems accessing anonymous testing in a specific area. The Department may either ask a provider to provide anonymous testing, or agree to a request from a provider where the same circumstances exist. A State-designated site must accept the Department's standards, which are based on the CDC guidelines for the provision of HIV testing, counseling, referral and partner notification and the Department may choose to grant that provider the funds to carry out the services. The CDC guidelines are available from the Department.

Anonymous HIV-testing sites may also provide confidential testing.

The number of anonymous test sites is over 130, located throughout the Commonwealth. These include the Department's state health centers, local health departments, and sites operated by publicly funded providers. This number fluctuates because of the constant addition and deletion of sites due to changes in these agencies and the turn-over of qualified counseling staff. The six county (Philadelphia, Allegheny, Bucks,

* * *

HIV SERVICES – THE RANGE OF SERVICES, INCLUDING PREVENTION, COUNSELING, TESTING, TREATMENT, CASE MANAGEMENT, SUPPORT AND REFERRAL SERVICES, WHICH ARE PROVIDED TO PERSONS INFECTED WITH OR AFFECTED BY HIV OR AIDS, AND ARE INTENDED TO ALLEVIATE PHYSICAL AND PSYCHOSOCIAL PROBLEMS CREATED BY THESE DISEASES AND CONDITIONS.

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).

* * *

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~~ THE POTENTIAL PERINATAL TRANSMISSION OF HIV TO A NEWBORN INDICATED BY A POSITIVE HIV TEST RESULT FOR THE PREGNANT WOMAN OR MOTHER OF A NEWBORN.

* * *

STATE-DESIGNATED ANONYMOUS HIV TESTING SITE -- AN HIV TESTING SITE SUPPORTED BY THE DEPARTMENT EITHER THROUGH DIRECT FUNDING OR PAYMENT FOR TESTING, WHICH PROVIDES ANONYMOUS AND CONFIDENTIAL TESTING AND WHICH AGREES TO ADHERE TO THE CDC'S COUNSELING AND TESTING STANDARDS AND GUIDELINES ISSUED BY THE DEPARTMENT.

* * *

SUBCHAPTER B. REPORTING OF DISEASES

§27.21. ~~Reporting of AIDS cases by physicians and hospitals~~ (RESERVED).

HIV (HUMAN IMMUNODEFICIENCY VIRUS) (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

(c) ~~The UNLESS OTHERWISE PROVIDED FOR IN THIS CHAPTER, THE~~ report shall include the following, EXCEPT AS PROVIDED IN SUBSECTION (D):

(1) The name, age, address, and telephone number of the person from whom the specimen was obtained.

(2) The date the specimen was collected.

(3) The source of the specimen (such as, serum, stool, CSF, wound).

(4) The name of the test or examination performed and the date it was performed.

(5) The results of the test.

(6) The range of normal values for the specific test performed.

(7) The name, address, and telephone number of the physician for whom the examination or test was performed.

(8) Other information requested in case reports or formats specified by the Department.

(d) ~~The report shall be submitted~~ LABORATORY TEST RESULTS SHALL BE REPORTED by the person in charge of a laboratory ~~in either a hard copy format or an electronic transmission format specified by the Department.~~ DIRECTLY TO THE DEPARTMENT'S BUREAU OF EPIDEMIOLOGY THROUGH SECURE ELECTRONIC MECHANISMS IN A MANNER SPECIFIED BY THE DEPARTMENT, EXCEPT FOR THE FOLLOWING:

~~(e) Reports made on paper shall be made to the LMRO where the case is diagnosed or identified. Reports made electronically shall be submitted to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology~~. Reports of maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell hemoglobinopathies, cancer, CD4 T-LYMPHOCYTE TEST RESULTS WITH A COUNT OF LESS THAN 200 CELLS/UL OR LESS THAN 14% OF TOTAL LYMPHOCYTES, HIV (HUMAN IMMUNODEFICIENCY VIRUS), and lead poisoning shall be ~~reported~~ MADE IN THE MANNER AND to the location specifically designated in this subchapter. See §§27.30, 27.31, 27.32A

(A) REPORTING BY CLINICAL LABORATORIES.

(1) A PERSON IN CHARGE OF A CLINICAL LABORATORY SHALL REPORT CD4 T-LYMPHOCYTE TEST RESULTS AS DEFINED BY §27.22(B) (RELATING TO REPORTING OF CASES BY CLINICAL LABORATORIES) ELECTRONICALLY TO THE HIV/AIDS EPIDEMIOLOGY SECTION, DIVISION OF INFECTIOUS DISEASE EPIDEMIOLOGY, BUREAU OF EPIDEMIOLOGY, WITHIN 5 DAYS OF OBTAINING THE TEST RESULTS.

(2) A PERSON IN CHARGE OF A CLINICAL LABORATORY SHALL REPORT POSITIVE TEST RESULTS OFANY 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, WITHIN 5 DAYS OF OBTAINING THE TEST RESULTS.

(3) 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.

(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.

INDIVIDUAL AND SUBMITTED IT FOR LABORATORY TESTING.

(XII) 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.

~~(XIII) ANY OTHER INFORMATION THE DEPARTMENT DETERMINES TO BE RELEVANT.~~

(3) IN ADDITION TO REPORTING THE AIDS DIAGNOSIS OR THE RECEIPT OF TEST RESULTS, THE REPORTER SHALL MAINTAIN THE DATA REQUIRED IN PARAGRAPH (2) IN THE PATIENT FILE ON THE DEPARTMENT'S HIV/AIDS REPORT FORM.

(4) 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 PARAGRAPH (2) ELECTRONICALLY TO THE DEPARTMENT'S BUREAU OF EPIDEMIOLOGY THROUGH A SECURE ELECTRONIC MECHANISM SPECIFIED BY THE DEPARTMENT.

~~§27.32a~~ §27.32B. Confidential and anonymous testing.

(a) Anonymous testing for HIV, except for blinded HIV testing authorized under section 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. A person or entity 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, UNLESS IT IS A STATE-DESIGNATED ANONYMOUS HIV-TESTING SITE.

(b) Anonymous test results shall be reported in accordance with ~~§27.32~~ §27.32A(B)(2) (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~~ . IN LIEU OF THE INFORMATION REQUIRED IN §27.32A(B)(2)(I), THE REPORT OF AN ANONYMOUS TEST SHALL INCLUDE an ~~anonymous code assigned at the time the specimen is collected in accordance with a Department-approved anonymous test site algorithm~~ ASSIGNED NUMBER PREPRINTED ON THE HIV COUNSELING AND TESTING REPORT FORM. THE REPORT SHALL ALSO INCLUDE THE INDIVIDUAL'S COUNTY OF RESIDENCE.

C. THE DEPARTMENT MAY CREATE AND FUND AN ADDITIONAL ANONYMOUS HIV-TESTING SITE IN A PARTICULAR AREA WHEN IT FINDS, BASED ON DEMOGRAPHIC INFORMATION REPORTED TO IT UNDER THIS CHAPTER, THAT THERE IS A LACK OF ACCESS TO ANONYMOUS HIV TESTING IN THAT PARTICULAR AREA.

(1) THE DEPARTMENT MAY BEGIN THE PROCESS OF DESIGNATING AN ANONYMOUS HIV TESTING SITE EITHER BY CONTACTING A PROVIDER OR BY RESPONDING TO A REQUEST FROM A PROVIDER TO INCREASE THE NUMBER OF SITES IN THE GEOGRAPHIC AREA SPECIFIED BY THE REQUEST.

(2) IF A PROVIDER IS DESIGNATED AS AN ANONYMOUS HIV-TESTING SITE, THE PROVIDER SHALL ADHERE TO THE CDC'S GUIDELINES FOR COUNSELING, TESTING, REFERRAL AND PARTNER NOTIFICATION AND TO THE TERMS SET OUT BY THE DEPARTMENT IN ANY GRANT AGREEMENT.

~~§27.32b~~§27.32C. 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~~§27.32D. Department authority to require complete reporting.

~~To~~ THE DEPARTMENT WILL HAVE ACCESS TO AND MAY REVIEW THE PATIENT RECORDS OF PHYSICIANS, HOSPITALS,

ANNEX A

TITLE 28. HEALTH AND SAFETY

* * *

PART III. PREVENTION OF DISEASES

* * *

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

§27.1. Definitions.

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

* * *

AIDS (ACQUIRED IMMUNE DEFICIENCY SYNDROME) – AS DEFINED BY THE CDC CASE DEFINITION PUBLISHED IN THE CDC MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR). (THE DEPARTMENT WILL PUBLISH IN THE *PENNSYLVANIA BULLETIN* A REFERENCE TO A CDC UPDATE OF THE CASE DEFINITION WITHIN 30 DAYS OF ITS PUBLICATION IN THE MMWR).

ANONYMOUS HIV TESTING -- HIV TESTING PERFORMED AT A STATE-DESIGNATED HIV TESTING SITE FOR AN INDIVIDUAL WHO CHOOSES NOT TO PROVIDE HIS NAME IN GIVING CONSENT FOR THE TESTING.

CDC – Centers for Disease Control and Prevention.

* * *

CONFIDENTIAL HIV TESTING. HIV TESTING PERFORMED FOR AN INDIVIDUAL WHO, IN GIVING HIS CONSENT FOR THE TESTING, PROVIDES HIS NAME AND OTHER PERSONAL OR DEMOGRAPHIC IDENTIFIERS.

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

* * *

FDA – Food and Drug Administration.

* * *

HIV SERVICES – THE RANGE OF SERVICES, INCLUDING PREVENTION, COUNSELING, TESTING, TREATMENT, CASE MANAGEMENT, SUPPORT AND REFERRAL SERVICES, WHICH ARE PROVIDED TO PERSONS INFECTED WITH OR AFFECTED BY HIV OR AIDS, AND ARE INTENDED TO ALLEVIATE PHYSICAL AND PSYCHOSOCIAL PROBLEMS CREATED BY THESE DISEASES AND CONDITIONS.

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).

* * *

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~~ THE POTENTIAL PERINATAL TRANSMISSION OF HIV TO A NEWBORN INDICATED BY A POSITIVE HIV TEST RESULT FOR THE PREGNANT WOMAN OR MOTHER OF A NEWBORN.

* * *

STATE-DESIGNATED ANONYMOUS HIV TESTING SITE -- AN HIV TESTING SITE SUPPORTED BY THE DEPARTMENT EITHER THROUGH DIRECT FUNDING OR PAYMENT FOR TESTING, WHICH PROVIDES ANONYMOUS AND CONFIDENTIAL TESTING AND WHICH AGREES TO ADHERE TO THE CDC'S COUNSELING AND TESTING STANDARDS AND GUIDELINES ISSUED BY THE DEPARTMENT.

* * *

SUBCHAPTER B. REPORTING OF DISEASES

§27.21. ~~Reporting of AIDS cases by physicians and hospitals~~ (RESERVED).

~~A physician or a hospital is required to report a case of AIDS within 5 work days after it is identified to the local health department if the case resides within the jurisdiction of that local health department. In all other cases, the physician or hospital shall report the case to the HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.~~

§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:

* * *

(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.

* * *

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 (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

HIV (HUMAN IMMUNODEFICIENCY VIRUS) (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

PERINATAL EXPOSURE OF A NEWBORN TO HIV (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

§27.22. Reporting of cases by clinical laboratories.

(a) A person who is in charge of a clinical laboratory in which a laboratory ~~examination~~ 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 ~~examination~~ 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/*UL* OR LESS THAN 14% OF TOTAL LYMPHOCYTES (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

HIV (HUMAN IMMUNODEFICIENCY VIRUS) (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

* * *

(c) The report shall include the following, EXCEPT AS PROVIDED IN SUBSECTION (D):

(1) The name, age, address, and telephone number of the person from whom the specimen was obtained.

(2) The date the specimen was collected.

(3) The source of the specimen (such as, serum, stool, CSF, wound).

(4) The name of the test or examination performed and the date it was performed.

(5) The results of the test.

(6) The range of normal values for the specific test performed.

(7) The name, address, and telephone number of the physician for whom the examination or test was performed.

(8) Other information requested in case reports or formats specified by the Department.

(d) ~~The report shall be submitted~~ LABORATORY TEST RESULTS SHALL BE REPORTED by the person in charge of a laboratory ~~in either a hard copy format or an electronic transmission format specified by the Department.~~ DIRECTLY TO THE DEPARTMENT'S BUREAU OF EPIDEMIOLOGY THROUGH SECURE ELECTRONIC MECHANISMS IN A MANNER SPECIFIED BY THE DEPARTMENT, EXCEPT FOR THE FOLLOWING:

~~(e) Reports made on paper shall be made to the LMRO where the case is diagnosed or identified. Reports made electronically shall be submitted to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology~~. Reports of maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell hemoglobinopathies, cancer, CD4 T-LYMPHOCYTE TEST RESULTS WITH A COUNT OF LESS THAN 200 CELLS/UL OR LESS THAN 14% OF TOTAL LYMPHOCYTES, HIV (HUMAN IMMUNODEFICIENCY VIRUS), and lead poisoning shall be ~~reported~~ MADE IN THE MANNER AND to the location specifically designated in this subchapter. See §§27.30, 27.31, 27.32A and 27.34 (relating to reporting cases of certain diseases in the newborn child;

reporting cases of cancer, REPORTING AIDS, HIV, CD4 T-LYMPHOCYTE COUNTS, AND PERINATAL EXPOSURE OF NEWBORNS TO HIV and reporting cases of lead poisoning).

~~(f)~~(E) A clinical laboratory shall submit isolates of salmonella and shigella to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

~~(g)~~(F) A clinical laboratory shall submit isolates of Neisseria meningitidis obtained from a normally sterile site to the Department's Bureau of Laboratories for serogrouping within 5 work days of isolation.

~~(h)~~(G) A clinical laboratory shall send isolates of enterohemorrhagic E. coli to the Department's Bureau of Laboratories for appropriate further testing within 5 work days of isolation.

~~(i)~~(H) A clinical laboratory shall send isolates of Haemophilus influenzae obtained from a normally sterile site to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

~~(j)~~(I) The Department, upon publication of a notice in the *Pennsylvania Bulletin*, may authorize changes in the requirements for submission of isolates based upon medical or public health developments when such departure is determined by the Department to be necessary to protect the health of the people of this Commonwealth. The change will not remain in effect for more than 90 days after publication unless the Board acts to affirm the change within that 90-day period.

* * *

§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/*U*L OR LESS THAN 14% OF TOTAL LYMPHOCYTES, HIV TEST RESULTS OR PERINATAL EXPOSURE OF A NEWBORN TO HIV, 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):

* * *

§27.32A. REPORTING AIDS, HIV, CD4 T-LYMPHOCYTE COUNTS, 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 BY §27.22(B) (RELATING TO REPORTING OF CASES BY CLINICAL LABORATORIES) ELECTRONICALLY TO THE HIV/AIDS EPIDEMIOLOGY SECTION, DIVISION OF INFECTIOUS DISEASE EPIDEMIOLOGY, BUREAU OF EPIDEMIOLOGY, WITHIN 5 DAYS OF OBTAINING THE TEST RESULTS.

(2) A PERSON IN CHARGE OF A CLINICAL LABORATORY SHALL REPORT POSITIVE TEST RESULTS OFANY 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, WITHIN 5 DAYS OF OBTAINING THE TEST RESULTS.

(3) 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.

(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) THE NAME OF THE PERSON OR ENTITY SUBMITTING THE SPECIMEN FOR TESTING.

(X) THE ADDRESS OF THE PERSON OR ENTITY SUBMITTING THE SPECIMEN FOR TESTING, INCLUDING THE ZIP CODE, PHYSICAL ADDRESS AND TELEPHONE NUMBER OF THE SUBMITTER.

(4) 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 (A)(3), WITH THE EXCEPTION OF SUBPARAGRAPHS (VI) THROUGH (IX). IN ADDITION TO THE INFORMATION INCLUDED IN SUBSECTION (A)(3), 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.

(B) REPORTING BY PHYSICIANS, HOSPITALS, PERSONS OR ENTITIES, WHO DIAGONOSE AIDS OR WHO RECEIVE OR PROVIDE HIV AND CD4 T-LYMPHOCYTE TEST RESULTS.

(1) A PHYSICIAN, HOSPITAL, PERSON PROVIDING HIV SERVICES OR PERSON IN CHARGE OF AN ENTITY PROVIDING HIV SERVICES, WHO MAKES A DIAGNOSIS OF AIDS OR WHO RECEIVES HIV OR 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 WITHIN 5 BUSINESS 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 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

(III) 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 (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

(IV) A PERINATAL EXPOSURE OF A NEWBORN TO HIV (EFFECTIVE 90 DAYS FROM THE DATE OF PUBLICATION OF THESE REGULATIONS AS FINAL IN THE *PENNSYLVANIA BULLETIN*).

(2) 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:

(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.

(III) THE INDIVIDUAL'S DATE OF BIRTH.

(IV) THE INDIVIDUAL'S SEX.

(V) THE INDIVIDUAL'S RACE OR ETHNICITY.

(VI) THE DATE OF EACH TEST PERFORMED.

(VII) THE TYPE OF TEST OR TESTS PERFORMED.

(VIII) THE TEST RESULTS.

(IX) THE PATIENT'S HISTORY ON PROBABLE MODES OF TRANSMISSION.

(X) THE TREATMENT PROVIDED.

(XI) 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.

(XII) 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.

(3) IN ADDITION TO REPORTING THE AIDS DIAGNOSIS OR THE RECEIPT OF TEST RESULTS, THE REPORTER SHALL MAINTAIN THE DATA REQUIRED IN PARAGRAPH (2) IN THE PATIENT FILE ON THE DEPARTMENT'S HIV/AIDS REPORT FORM.

(4) 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 PARAGRAPH (2) ELECTRONICALLY TO THE DEPARTMENT'S BUREAU OF EPIDEMIOLOGY THROUGH A SECURE ELECTRONIC MECHANISM SPECIFIED BY THE DEPARTMENT.

~~§27.32a~~ §27.32B. Confidential and anonymous testing.

(a) Anonymous testing for HIV, except for blinded HIV testing authorized under section 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. A person or entity 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, UNLESS IT IS A STATE-DESIGNATED ANONYMOUS HIV-TESTING SITE.

(b) Anonymous test results shall be reported in accordance with ~~§27.32~~ §27.32A(B)(2) (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~~. IN LIEU OF THE INFORMATION REQUIRED IN §27.32A(B)(2)(I), THE REPORT OF AN ANONYMOUS TEST SHALL

INCLUDE an ~~anonymous code assigned at the time the specimen is collected in accordance with a Department-approved anonymous test site algorithm~~ ASSIGNED NUMBER PREPRINTED ON THE HIV COUNSELING AND TESTING REPORT FORM. THE REPORT SHALL ALSO INCLUDE THE INDIVIDUAL'S COUNTY OF RESIDENCE.

C. THE DEPARTMENT MAY CREATE AND FUND AN ADDITIONAL ANONYMOUS HIV-TESTING SITE IN A PARTICULAR AREA WHEN IT FINDS, BASED ON DEMOGRAPHIC INFORMATION REPORTED TO IT UNDER THIS CHAPTER, THAT THERE IS A LACK OF ACCESS TO ANONYMOUS HIV TESTING IN THAT PARTICULAR AREA.

(1) THE DEPARTMENT MAY BEGIN THE PROCESS OF DESIGNATING AN ANONYMOUS HIV TESTING SITE EITHER BY CONTACTING A PROVIDER OR BY RESPONDING TO A REQUEST FROM A PROVIDER TO INCREASE THE NUMBER OF SITES IN THE GEOGRAPHIC AREA SPECIFIED BY THE REQUEST.

(2) IF A PROVIDER IS DESIGNATED AS AN ANONYMOUS HIV-TESTING SITE, THE PROVIDER SHALL ADHERE TO THE CDC'S GUIDELINES FOR COUNSELING, TESTING, REFERRAL AND PARTNER NOTIFICATION AND TO THE TERMS SET OUT BY THE DEPARTMENT IN ANY GRANT AGREEMENT.

~~§27.32b~~§27.32C. 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~~§27.32D. Department authority to require complete reporting.

~~To~~ THE DEPARTMENT WILL HAVE ACCESS TO AND MAY REVIEW THE PATIENT RECORDS OF PHYSICIANS, HOSPITALS, PERSONS PROVIDING HIV SERVICES AND PERSONS IN CHARGE OF ENTITIES PROVIDING HIV SERVICES, WHO MAKE

DIAGNOSES OF AIDS, OR WHO RECEIVE OR PROVIDE HIV AND CD4 T-LYMPHOCYTE 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 ~~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~~ §27.32E. Record audits.

(a) The Department may conduct record audits of the records of physicians, hospitals, ~~and other~~ 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 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 TO ensure compliance with this chapter.

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

A. PURPOSE AND BACKGROUND

The Department's regulations 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 herein, or (3) who are pregnant women who have had positive HIV test results and whose newborns have been perinatally exposed to HIV. The regulations also clarify that cases of Acquired Immune Deficiency Syndrome (AIDS) are reportable based on the case definition of the Centers for Disease Prevention and Control (CDC). Reports of AIDS include reports of presumptive diagnoses of AIDS based on the presence of an AIDS defining illness (for example, Kaposi's sarcoma) with laboratory confirmation of HIV.

In holding to its proposal to require reporting of these conditions and infections by name, the Department is following recommendations of the 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. Reporting by name 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 joins 34 other 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 provides 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 information also provides 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.

B. SUMMARY

The majority of comments the Department received on its proposed regulations dealt with the Department's decision to require reporting by name. Other general comments were received on a variety of topics: the Department's decision to require reporting

electronically; the confidentiality and security of the information reported; the cost of the proposed rulemaking, and the lack of an exception in the proposed regulations to name reporting for research projects. The Department will discuss these general comments before addressing comments addressed to specific provisions of the proposed regulations.

The Department's rulemaking relating to HIV reporting and the other reporting addressed in these regulations is a very specific amendment to its broader regulations governing prevention, control and reporting of communicable and noncommunicable diseases within the Commonwealth. The Department proposed sweeping changes to update the entire regulatory scheme relating to communicable and noncommunicable diseases (28 Pa. Code Chapter 27) in May of 2000 (30 Pa. B. 2715 (May 27, 2000)). Final rulemaking followed and those amendments went into effect on January 26, 2002. Because of the importance of HIV reporting to the Commonwealth, the Department could not wait to propose additional amendments to Chapter 27 relating to HIV reporting until after the adoption of the broad changes to Chapter 27.

The timing of the Department's proposed rulemaking relating to HIV reporting, therefore, required that the Department propose changes to Chapter 27 as it read prior to the January 26, 2002 amendments. Consequently, in most cases, the text of regulations to which the Department is now adopting amendments is not the same text to which the Department proposed amendments.

In response to a comment from the Independent Regulatory Review Commission (Commission) asking how the Department would coordinate the two sets of rulemaking, and upon advice from the Commission, the Department has drafted Annex A to show only amendments to the current text of regulations that were altered following the proposed rulemaking. Amendments to those regulations that were not revised following proposed rulemaking are shown in the customary fashion. The preamble explains when an amendment is made to a regulation, or the text of a regulation, other than that to which the amendment was proposed.

Name reporting

The Department received many comments objecting to its proposal to require reporting by name of perinatal exposure of newborns to HIV, certain HIV test results and CD4 T-lymphocyte cell counts. These comments came from various groups of persons as well as individuals, including providers, legislators, one local health department, and public interest groups.

The Department also received comments in support of its proposed regulations. Various professional medical associations, provider groups, local health departments, and public interest groups supported the Department's proposal to require reporting by name. The Health and Welfare Committee of the Pennsylvania State Senate supported the proposals contingent upon the Department taking appropriate steps to make anonymous testing a readily available option to those who might otherwise avoid HIV testing, and ensuring that information regarding anonymous testing is available to at risk populations.

The Department has listed the comments both in opposition to and in support of confidential name reporting below, eliminating repetitive remarks where possible, and has answered these comments in one comprehensive response.

Comments in opposition

The Department should justify the need for names and addresses of individuals in the reports and then explain how the reports will be maintained.

Research shows that requiring name reporting deters people from taking HIV tests. Requiring name reporting will undermine hard work done in the Delaware Valley to encourage people to access HIV services. There are 10 states and territories that have chosen to require reports by unique identifier, including Maryland, Vermont, Illinois and California, and this method of reporting does provide accurate data.

Name reporting will delay treatment. The outcry by medical providers, service providers and people living with HIV/AIDS is telling. It is inconceivable that name reporting will not harm lives.

HIV reporting is necessary, but not by name. The Allegheny County Health Department's approach of requiring reporting by unique identifier is better, and should be followed.

Name reporting, even with the availability of anonymous test sites, frightens people, and will deter persons from getting tested, because they are not convinced that confidentiality can be assured.

Name-based reporting will cause women to refuse or forgo prenatal care. This is a concern because convincing pregnant women to take an HIV test has reduced the number of vertical transmissions of HIV.

The Department should explain why a reporting system based on unique identifiers will not accomplish its objectives. Supporters recognize that anonymous testing should augment name-based reporting. But a unique identifier system would reduce the need for anonymous testing.

The CDC recognizes that a unique identifier system will provide necessary information to the public health system to control the spread of disease. The Department should institute a unique identifier system.

Because peer review publications are evenly split on the question of whether persons will be deterred from testing by required name reporting, the Department should err on the side of caution and develop a unique identifier system.

A unique identifier system would protect the confidentiality of persons living with HIV while also providing effective tracking of the epidemic. Pennsylvania could benefit from the California experience where reporting is done by a unique identifier.

A unique identifier system will not cause the Department to lose funding. The Department will only lose funding if no information is reported by the Department to the Federal government. Funding will be a problem under a name reporting system, because, if less people choose to be tested, the Department will have less cases to report. The Department must set up a system that encourages the maximum number of persons to be tested.

Reporting by unique identifier in the initial phase of the continuum of care provides the most precise data available, ensuring that credible information is secured for planning and capturing maximum funding resources.

Although some reported figures show "improved" statistics regarding HIV cases after name reporting is instituted, these figures are misleading. Most often this methodology followed a period of no required reporting, so an improvement in statistics would occur as a matter of course.

The Department's decision to propose name reporting as the method by which cases of HIV would be reported goes contrary to public testimony offered at the Department's

meetings. Ninety-five percent of the people at those public meetings opposed name reporting.

Reporting by name will increase the potential for breaches of confidentiality. Discrimination could occur if the security and confidentiality of information maintained by the Department was breached in some way.

Disenfranchised populations will not be tested if there is the slightest indication that their names could become public knowledge. This will harm the most marginalized populations, including, for example, persons who use illegal drugs.

Name reporting threatens the right to privacy.

Name reporting interferes with the physician-patient relationship.

Comments in support

Confidential name reporting will enhance the Department's opportunities to provide case management services to patients, including getting patients into more services and tracking them to determine quality of care, without fear of breach of confidentiality.

The Department has been thorough in its review of the benefits and shortcomings of reporting based on names and on unique identifiers. The Department has prudently made

the determination that name reporting is the best option, based on public health reasons. Public perception and fear should not drive policy.

Name reporting in delivering direct medical and respite care allows medical professionals to treat HIV clients in the same manner as clients treated for all other communicable diseases, providing the same standard of care.

The Department is to be commended for providing assistance to local health departments through the implementation of these regulations. Name-based reporting will give local health departments information that they now have to guess at. Name-based reporting allows provision of case management services to infected persons and their partners.

The product of ongoing and systematic collection of the information that will result from name-reporting is valid, timely and complete data, and is the key facet to any disease surveillance system. The problem in the Commonwealth has been the fact that HIV was not reportable, despite the fact that sound epidemiologic principles and public health practice necessitates the reporting of communicable diseases that are a public health concern. A name-based reporting system of people with infectious diseases has great potential to benefit both the individual and the public health system. A name-reporting system would result in more people benefiting from early intervention programs.

In a unique identifier system, persons tested anonymously supply in a code, parts of the name, social security number, date of birth, sex and race. The non-name identifier

system is not anonymous as it may be possibly linked to a specific individual. To do record follow-up for missing information, such as HIV-risk, or to provide follow-up care, coded records need to be linked to an individual's name. This is usually found in a log maintained by providers or other reporting sources. Multiple logs with names may create multiple opportunities for breaches of confidentiality.

Name-based reporting would enable public health employees to find and counsel people who are tested but do not return for their results; would enable public health employees to interview clients to assess their need for a variety of community services, including, for example, housing, transportation, medical treatment, tuberculosis testing, and other assistance; could aid partner notification programs; and would aid public health employees in educating HIV-infected women about the risks of pregnancy, and how to minimize the risks of transmission.

Data from a 1998 study of the implementation of name-based HIV reporting in Louisiana, Nevada, New Jersey, Tennessee, Michigan and Nebraska indicated that the impact of surveillance on those seeking HIV testing will be small, and should not hinder HIV prevention efforts.

The impact of HIV-reporting by name is likely to vary from community to community, and risk group to risk group. What matters, however, is that prevention practices can help someone, somewhere, at sometime, and this can only happen with name-based reporting. To allow the Commonwealth to target programs and resources most

effectively, the public health system must keep pace with where the HIV epidemic is going. Improvement of the ability to track early HIV infection before it progresses to AIDS is essential.

The Department should be congratulated for its strong leadership in the face of opposition. Only confidential name-based reporting has the capability of contributing to the control of HIV transmission. The Department can perform contact tracing and partner notification, assist in linkages to treatment and other services, including prevention, case management, and assistance with medication compliance. Name-reporting allows the Department to provide outreach to infected persons, obtain risk factor history information, eliminate duplicate reports and monitor disease trends.

The Department can be trusted to use every mechanism available to it to ensure the confidentiality of reported information, as it has done with information reported on AIDS patients.

Confidential name-based reporting is similar to other reporting requirements in the Commonwealth, and follows the recommendations established by the CDC. The Commonwealth will join 34 other states who also require name-based reporting. Name-based reporting allows for the most accurate tracking and will promote increased opportunities for disease intervention, and for funding.

Attempts to control the spread of HIV should not be entangled with politics. The Department's regulations will correct that, and allow epidemiologists to finally understand the extent of the spread of the infection in the Commonwealth. Name reporting allows for critical health practices, such as contact tracing, confirmation of treatment and assurance of services.

A unique identifier reporting system has failed in Texas, and is believed by the state medical society and the health officers of Maryland to be failing there as well. Codes within a unique identifier system require maintenance by providers of lists of names and codes, which increases the chances of breaches of confidentiality. A confidential name-based system is more secure and more confidential.

Response

The Department has not changed these regulations based on these comments. The Department is aware that the majority of the persons presenting testimony at the public meetings it held prior to proposed rulemaking were not in favor of name reporting. The Department did consider these comments in coming to its decision to propose confidential name reporting of the diseases, infections and conditions addressed in this rulemaking. The Department has carefully reviewed all known options for reporting HIV. After considering all of the information, concerns and recommendations that it received, as well as its own expertise and experience, the Department concluded that confidential name-based reporting is the best method for reporting HIV in the Commonwealth.

The Department disagrees that a unique identifier system would neither cause the Department to lose funding nor be less accurate than a system of reporting by name. A confidential name-based reporting system collects more accurate data since availability of the patient's name facilitates timely completeness of case reporting and allows the Department to review and eliminate duplicate case reports. If data is not timely, it is neither complete nor accurate for the Department's purposes. The data obtained under name-based reporting is more appropriate for the Department's needs. It fosters a more complete and accurate description of the epidemic for prevention and care planning, resource allocation, trend analysis and increased Federal funding; and Department facilitation of linkage to prevention and care services.

Further, the funding the Department obtains is better spent on prevention and treatment efforts than on developing a unique identifier reporting system. The confidential name-reporting system, which is already in place for other diseases, including AIDS, can provide accurate data at relatively small cost. Spending funds to develop a unique identifier based-reporting system is neither effective nor efficient in the fight to prevent and control the spread of HIV and AIDS.

A reporting system based on unique identifiers would be complex in comparison with the name-based systems currently in place, and would create problems for providers who are used to the current system of name-based reporting. This could lead to untimely reporting and underreporting, which, in turn, could lead to a loss in funding. Cases not

reported before a certain date during each grant period are lost to the Department for the purposes of funding.

The confidentiality and security of data kept in secure Department databases is greater than data maintained in the multiple lists linking names of cases to unique identifiers, which would most likely need to be developed and maintained at multiple provider sites to accomplish linkage of individuals with health care and other services, and to allow for follow-up. Therefore, name-based reporting is better able to meet the higher standards for confidentiality and security set by the CDC.

Name-based reporting will also be easier for providers and for public health agencies to use than a system based on unique identifiers. Reporters in the Commonwealth have used name-based reporting for AIDS and all other reportable diseases and conditions. While reporting by unique identifier would require the development of a new reporting system, and would require additional logs or other systems by which providers could cross check unique identifiers with names, name-based reporting will simply add additional diseases, infections or conditions to the current reporting system. Name-based reporting will eliminate the need for extensive training and the creation of separate databases to maintain logs of names, and will allow for complete reporting by the provider.

With respect to concerns that name-based reporting will deter persons from seeking testing and will delay treatment, there is no conclusive evidence to show that name

reporting does deter persons from seeking an HIV test. There is, however, growing evidence showing that name-based reporting can facilitate structured programs for linkage to care and prevention services. The Department will monitor the potential for deterrence of test seeking behavior on an ongoing basis using a CDC protocol that is available for HIV reporting states. Further, the Department will seek to ensure that anonymous testing is available throughout the Commonwealth for those persons who choose not to test under their own names.

The availability of anonymous HIV testing sites is more fully explained in the discussion of §27.32b (relating to confidential and anonymous testing). However, the Department commits to ensuring that anonymous HIV testing will be available to individuals in every county who choose to be tested anonymously, rather than confidentially.

Concerns that confidential name-based reporting will interfere with the physician-patient relationship, and the right to privacy, are addressed in the Department's responses to comments on § 27.32e (relating to record audits). Although the comments on that section were specifically directed to the Department's authority to "look back" at providers' records from the effective date of the regulations to January 1, 2000, the Department's response applies to these more general statements as well.

Concerns that information reported to the Department will be disclosed improperly and that discrimination will occur are without foundation based upon the Department's record. Several commentators have acknowledged that the Department's record on

confidentiality is "sterling." The Department agrees with the commentators who have stated that public perception and fear should not drive public policy. The Department understands concerns that information could be used to discriminate against individuals. The Department takes its responsibility not to release information reported to it very seriously.

There is a misperception among some persons that confidential name-based reporting is a threat to privacy and widespread discrimination will follow its implementation. The Department intends to combat this misperception by a public information campaign. The Department is exploring ways to reassure the public that HIV/AIDS reporting data are maintained under the highest security and confidentiality standards. There has never been a violation of privacy from the public health reporting system in this Commonwealth in 20 years of name-based AIDS reporting.

Finally, the Department currently meets, and will ensure that it continues to meet, CDC standards for security for reportable information.

Electronic reporting and security

Comment

Given the Department's record with HIV software systems in the area of HIV services, specifically Lifeplan, we question whether systems implementation will accurately track the data in question.

Response

The Department has not changed the regulations in response to this comment. The Bureau of Epidemiology has an excellent track record on the implementation of its surveillance responsibilities and use of software for tracking purposes. The Lifeplan system is a client-level data system used to report to the Department and then to the Health Resources and Services Administration (HRSA) data on client care services. The CDC -provided HARS software application is a proven, Nationally used tool. It is used to collect surveillance data.

Comment

We have used the HARS system with the Allegheny County Health Department, and we find it difficult to implement in a clinic setting. Data retrieval is difficult.

Response

The Department has not changed the regulations in response to this comment. HARS software is a surveillance application and is not intended to be used by providers for clinic management. The Department will prepare a subset of HARS to be used by providers so that reporting will be easier for them.

Comment

Even if electronic reporting simplifies the reporting process, there will be a need for additional computers to report remotely.

Response

The Department has not changed the regulations in response to this comment. The Department understands that additional computers may be necessary for some providers. The Department, however, believes that the simplification of the reporting process outweighs any minor cost incurred by individual providers.

Comment

The Department needs to ensure that reports can be submitted even if some of the information is not available.

Response

Reporters will be able to submit reports electronically, even if all the information is not provided. The Department will continue to follow-up on case reports of HIV with missing information, as it currently does for other diseases.

Comment

The Department should develop and communicate a plan regarding how it intends to provide software and training.

Response

The Department agrees with the comment, and will be working with representatives of stakeholders to both formulate and implement software delivery and training.

Comment

Not all providers may be able to submit reports electronically. The Department should develop a mechanism that will allow for submission of reports in another manner.

Response

The Department will work with those providers unable to submit reports electronically. The Department is prepared to accept a diskette by mail from those providers without internet service. The Department's general regulation on reporting (28 Pa. Code §27.4) allows for reporting incomplete information on cases by telephone although complete reporting will be required electronically through, for example, the use of diskettes, or through the use of a telephone number provided by the Department at no charge which would permit access to a web-based application to be used for reporting.

Comments

The regulations should specify security standards applicable to required electronic transmissions.

The regulations fail to describe the security systems that will be used to protect the medical information that will be transmitted electronically.

How will electronic reporting be done, and how will the Department assure the confidentiality and security of electronically reported information?

Response

Security of medical information and confidentiality of medical records and disease reports is a concern for both providers and the Department and local health departments. The Department is well aware of its responsibility to protect the confidentiality of the reports and information submitted to it. The security of electronic reporting will be accomplished through the use of encryption, and also the use of a digital certificate for each provider, which has, as part of its configuration, imbedded security similar to that used by banks for the electronic transfer of funds. This security, often referred to as PKI (Personal Key Identification), requires two keys to open files. One is held by the provider, the other by the Department. This same PKI process will be used for all electronic disease reporting to the Department. It is state-of-the-art technology.

Comment

The Department must include in its regulations a commitment to meet CDC data security standards.

Response

The Department has not changed the regulation in response to this comment. The Department already meets CDC security standards for HIV/AIDS case reports. As a condition of its CDC surveillance grant, the Department must meet these requirements, and adhere to them. As confirmed by the CDC, the Department is in compliance with these CDC requirements as of the last site visit from the CDC, which occurred in May of 2000. The county and municipal departments of health, which will act as local morbidity

report offices (LMROs), are also in compliance with these standards, as of the Department's latest audit of each department.

Comment

What equipment and software will providers be required to use, how much training will be required, and how often will it be offered? How much will this cost, and who will bear the cost, the Department or the reporters?

Response

The Department will provide the software to the provider free-of-charge. Instruction booklets or sheets will accompany the software. The Department will develop training schedules in consultation with stakeholder groups. The only cost to the provider will be transportation to the training site, and the cost of a computer with sufficient operating capacity and speed and an internet connection. It is expected that most providers will be able to use their existing computers for disease reporting. The Department is, however, prepared to accept diskettes by mail for those providers without internet service.

Confidentiality

Comments

How will these regulations affect previously tested persons already in care? How will they assure the confidentiality of their medical records?

Although the Department has had a positive record on confidentiality, the current regulations change the protections offered previously. Individuals who are HIV infected have faced discrimination once their HIV status has been learned.

If the Department goes forward with name reporting, measures to strengthen Statewide privacy protections for public health data must be examined immediately.

Response

The Department has not changed the regulations in response to these comments. Persons previously tested and in care will either be located through the Department's audit back to January 1, 2000, when additional testing is done to monitor the individual's status, or when the individual progresses from HIV to AIDS.

The Department has required the reporting of AIDS cases for roughly 20 years. The proven system for AIDS reporting has a 20-year track record of security and confidentiality, which includes stringent security and confidentiality features required by the CDC. The Department will protect the information reported on HIV in the same way, using the same CDC security standards, as they relate to HIV reporting. The security and confidentiality of the information will be maintained and, where necessary, improved in order to adequately handle the confidentiality of HIV case reports.

Comment

Since laboratories will now be required to transmit patient information, there is an increased risk for a breach of confidentiality. Although the ability to carry out this function is an integral part of laboratory services, the additional paper trails required by the newly mandated information sheets will challenge the ability to protect patient rights. The mere existence of special sheets attached to patient specimens may draw attention to the specimens, thus potentially violating patient confidentiality.

Response

Laboratories will be required to report results to the Department electronically. The patient information that will be sent to laboratories by providers is standard identifying information that is sent to laboratories in the normal course of business. The reason for including in the regulations language specifically requiring providers to submit this information to laboratories upon specimen submission is to ensure that this information is available for laboratories to send to the Department. This information is necessary in order to make the process of reviewing laboratory data for repeat case reports effective so that there is no need to contact providers about cases that have already been reported.

Laboratories will transmit this information to the Department electronically through secure data transmission portals. The system of electronic laboratory data transmission adopted by the Department is part of a National electronic laboratory reporting system being established by collaborating states and laboratories in conjunction with the CDC. The system meets the highest security and confidentiality standards for patient laboratory data transmission, as required by the CDC.

Comment

HIV reporting will not compromise confidentiality because appropriate safeguards currently exist. Reporting for other sexually transmitted diseases is required now, and we are not aware of any breach of confidentiality. National studies show that states with name reporting have not experienced any confidentiality problems.

Response

The Department agrees with the commentator.

Cost

Comments

It will take a good deal of time and resources to implement the regulations. The Department is requiring the reporting of all test results. Requiring duplicate reports seems costly. The regulations do not discuss the cost of this reporting, or how it will be funded. Providers with large numbers of patients will be adversely affected.

These regulations will have a major human and financial resources impact on high morbidity areas like Philadelphia. The Department does not say how it will financially support dual reporting.

The cost implications of the regulations are underestimated.

Our reporting system has been facilitated through cooperation with the Allegheny County Health Department, which performs on site data collection. Given the number of patients to whom we provide care, the information being required by these regulations will create an unmanageable workload for the clinic staff. Further, there is no provision for increasing staff in county health departments to collect this data.

Response

The Department does not believe the cost implications are underestimated, and has not changed the regulations in response to the comments. Further, these regulations are an addition to the existing list of over 50 reportable diseases, infections and conditions, and, for most reporters, additional infrastructure to accomplish this reporting should not be necessary.

The Department is sensitive, however, to provider concerns regarding funding. The Department has included in its budget funding to the local health departments, including Philadelphia County, for increased staff to handle additional workload. With respect to the comment relating to the large number of patients and clinic workload for private providers, current HIV cases will only need to be reported as they meet the AIDS case definition. The Department expects that will occur over an extended period of time and will not cause an undue burden. Further, county health departments will assist where that is possible. Electronic reporting by providers will limit any increased workload, since much of the information the Department is requiring will be collected for the patient's medical record, whether or not a reporting requirement exists.

With respect to the requirement that both laboratories and providers report the same case, the Department's reasons for requiring reporting by different types of reporters is discussed at greater length in responding to specific comments regarding multiple reporting and duplication of reports.

Comment

There will be an increased burden on research units and laboratories to implement reporting, including staff time and the cost of dedicated computer equipment and telephone lines for remote reporting.

Response

The Department has not changed the regulations in response to this comment. Dedicated computers and phone lines are not necessary, but password protection on provider databases is recommended. If the provider has an Internet Service Provider, the cost will be minimal.

Multiple reports

Comments

The Department should not require reporting of a case by more than one reporter.

The fiscal impact and purpose of the requirement of multiple reporters is not clear. Many persons may file reports on the same individual. What is the need for numerous reports

on a single case? What are the costs to the private sector when multiple reporters file and prepare reports? What will be the costs of effectively processing data from thousands of reporters in order to eliminate duplication?

Does the Department have a plan to figure out what to do when multiple reports are made of a single case?

Response

The Department currently requires the reporting by more than one type of reporter for every disease, infection and condition that is reportable under the law. This ensures that the Department will receive all the available material information relating to a case. The Department is concerned that if reporters "self-censor," based on their assumption that another person will make the report, there could be under-reporting. This would 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. It is better to get multiple reports providing the same information on a case, than to receive a single incomplete report.

With respect to the cost of reviewing several case reports to establish a single case file, that is a function which the Department currently performs for AIDS case reports. The Department has software that performs this function for it. There should be no additional

cost to the Commonwealth from filtering information from several case reports to develop a single comprehensive record.

Consent

Comment

Informed consent remains a hallmark of HIV testing protocols recommended by the CDC, and legislation relating to HIV testing. A system that allows individuals to bypass obtaining informed consent may undermine the trust and confidence between patients and their health care providers. Until the right of a patient to decline testing on a voluntary basis is revoked, the Department should not establish a system that may compromise this right.

Response

The Department has not changed the regulations in response to this comment. The regulations do not in any way prohibit or prevent a health care provider from obtaining consent from a patient before performing an HIV test. The Confidentiality of HIV-Related Information Act (35 P.S. §§7601-7612) (Act 148) still applies to the offering and provision of HIV testing, to the manner in which the results are given to the person tested, and to whether or not the information may be released to others. The regulations do not require an individual to take an HIV test of any kind, nor do they require an individual to take a test that will result in the name of the individual being reported to the Department. If a confidential test is chosen by the individual, the regulations require that the information establishing the presence of HIV be reported to the Department by the

individual's name. The regulations also require that the same results from an anonymous test be reported, although not by name. This is consistent with the requirements of Act 148.

Research exception

Comments

The regulations do not address problems that would arise for research programs if research programs are required to report the names of individuals who test positive for HIV infection or who have CD4 T-lymphocyte counts below a certain level. The regulations could alter a person's willingness to participate in a research project. The regulations should be modified to exclude research projects and research laboratories from reporting under an individual's name, data acquired for research purposes. This would not impact on the goal of reporting. Individuals participating in these studies would have been reported anonymously by their primary care provider or physician. Also, persons participating in these research projects already know their status, and, if they are positive, will be counseled to obtain medical care and will be provided information to facilitate their entry into the health care system.

Research studies use unique identifiers for all tests, and no demographic data is currently provided to diagnostic laboratories. Provision of such data to a laboratory is prohibited by informed consent documents signed by research subjects. Laboratories may be unable to accept additional information given terms of contracts and systems in place.

Research laboratories currently have no system in place to report communicable diseases. Data is generated solely for research protocols. All clinically relevant data is sent to the primary care provider after receiving written permission from the research subject.

Requiring that research facilities report HIV status will threaten their relationship with individuals who volunteer to participate in studies, and may result in an increase in HIV-infected individuals who are not receiving appropriate care.

New York has included a research exemption in its state statute.

Response

The Department has considered the comments recommending that research studies be exempted from reporting by name. The Department has decided against including such an exemption in the regulations. The Department has not provided for such exemptions for the reporting of other diseases, including AIDS. The Department does not believe that, at this time, there is sufficient evidence to show that the granting of such exemptions would further the public health purpose intended by these regulations. The Department, however, in determining whether such an exemption should be added at some future time, will consider any credible evidence research studies are able to provide to demonstrate that exempting research studies from name reporting from HIV will hamper the prevention and control of the spread of HIV. The Department understands that certain research studies begun prior to the effective date of these regulations may have been instituted under protocols that would prohibit the release of the information that the

Department is requiring. The Department will not require those studies to alter their protocols.

Section 27.1. Definitions.

This section includes definitions for Chapter 27. Three of the definitions proposed in the proposed rulemaking upon which this final rulemaking is predicated have already been adopted. They were adopted at Pa. B (January 26, 2002). Those terms were "district office," "local health department" and "local morbidity reporting office (LMRO)." Those terms and definitions, therefore, appear in the annex as existing regulation. A few commentators recommended changes to those definitions. The Department had either previously made the changes which were adopted in its final rulemaking on January 26, 2002, or has chosen not to revise the regulations. Those comments are discussed in greater detail below.

Comment

The Department should include the CDC case definition for AIDS in the regulations, rather than simply referring to it.

Response

The case definition for "AIDS" is the CDC definition. That definition is 15 pages long, and changes with new surveillance requirements or scientific needs. The Department has created a definition for "AIDS" in this section that incorporates by reference the CDC definition for "AIDS" published in its Morbidity and Mortality Weekly Report

(MMWR). This should enable persons to locate that definition if necessary. Historically, the CDC has revised the definition and published the revisions in the MMWR. Consequently, the Department has included with this definition a statement that it will publish references to the CDC MMWR updates to the case definition in the *Pennsylvania Bulletin* within 30 days of their publication.

The references for the current CDC case definitions are as follows:

> CDC. 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults. MMWR 1992;41 (RR-17).
>
> CDC. 1994 Revised Classification System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age. MMWR 1994;43 (RR-12).
>
> CDC. CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome. MMWR 1999;48 (RR-13).

Comment

The Department should expand the definition of "local morbidity reporting office (LMRO)" to minimize the potential for reporting to state health centers or other entities perceived to be county health departments. Inadvertent reporting to county offices might breach confidentiality, particularly in rural counties.

Response

The Department has not changed the definition in response to this comment. The definition of "LMRO" included in the regulations specifically identifies the district offices of the Department and the county/municipal health departments as LMROs. A list of these entities is available from the Department upon request, and the Department will publish a list in the *Pennsylvania Bulletin*. The Department does not agree that confusion will be likely to occur, especially since, with the exception of very few diseases, infections and conditions, all reporting is made to the LMROs.

Comment

The last sentence of the definition for "local health departments" referring to the Department maintaining a list, is substantive, and should be moved to the body of the regulations.

Response

The Department agrees with this comment. The sentence was deleted from the definition adopted on January 26, 2002.

Comments

To determine that a newborn has been exposed to HIV, as set forth in the definition for "perinatal exposure of a newborn to HIV," appears to require a subjective judgment by a broad array of persons. Substantive questions involving risk should not be included in a

definition. Reporters who are qualified to make the risk determination should be listed in the substantive part of the regulation.

Only information about newborns that come to term is useful in preventing a vertical transmission. Therefore, the definition should read as follows: "possible vertical transmission – potentially exposing a fetus to HIV during pregnancy of an HIV positive woman, regardless of the final serostatus of the infant."

Response

The Department has changed the definition to read: "The exposure of a newborn indicated by a positive HIV test result for the pregnant woman or mother of a newborn." The Department has made this change to clarify that, in determining whether a perinatal exposure has occurred, there is no determination of risk made. A newborn is considered exposed to HIV if the mother is HIV positive. The question of whether the child actually becomes HIV positive is a separate matter.

The Department has not changed the term defined to "potential vertical transmission." "Potential vertical transmission" is a term broader than "perinatal exposure." While "potential vertical transmission" applies to all types of mother-to-child transmission, "perinatal exposure" is limited to potential transmission in a perinatal setting. The Department has changed the definition to clarify that it is referring to potential perinatal transmissions by using the term "perinatal exposure."

The Department disagrees that only information regarding a newborn that has come to term is useful in preventing a vertical transmission,. The Department is requiring reporting of perinatal exposures, that is, potential perinatal transmissions. Information obtained on the status of the mother is instrumental in making prevention therapies available to the mother for the fetus.

Further, since some of these treatments are suspected of causing mutations in some children, reporting perinatal exposures will enable the Department to follow the women who tested positive and their children to collect data on this concern, and on the efficacy of other treatments. That information could provide data on whether, how, and why this occurs, and could lead to the development of safer treatment.

Comment

The Department should add definitions for the following terms: "unique identifier;" "confidential testing;" "anonymous testing;" and "State-designated anonymous testing sites."

Response

As has already been discussed, the Department has decided against the use of a unique identifier system in favor of a system of confidential name reporting. Therefore, the addition of a definition for the term "unique identifier" is not necessary.

The Department has added definitions of "anonymous HIV testing," "confidential HIV testing," and "State-designated anonymous HIV testing site" to eliminate confusion regarding anonymous and confidential testing, and the sites at which each or both may occur.

In anonymous HIV testing, an individual is informed that a fictitious name may be used to provide consent for the test. Although the individual is asked to provide information regarding age, sex, race, county, zip code, state of residence and the reason why the person believes that they are at risk for HIV, the individual may refuse to provide any of this information. Only an assigned number that is not linked to the person's identifying information identifies the person's written test result.

In confidential testing, the person signs a consent form with his or her name. Identifying information is collected and reported to the Department.

Anonymous HIV testing may only be conducted at a State-designated anonymous HIV-testing site. A State-designated anonymous HIV testing site is a testing site that has agreed to abide by the Department's guidelines for HIV testing, which are based on the CDC's guidelines, and that is supported by the Department, either through direct funding, or by having the laboratory tests paid for by the Department at the Department's contracted testing laboratory. Sites receiving other forms of public funding, for example, funding directly from the Federal government, or funding that does not require adherence

to the Department's guidelines relating to anonymous testing, are not State-designated anonymous HIV-testing sites.

State-designated anonymous HIV-testing sites allow for the Department and local health departments to be linked to an HIV case quickly, without the patient's name, since that individual has already become part of the public health system by his choice of testing site. The difficulties which reporting by unique identifier would raise for public health staff in obtaining the timely information that would make involvement of the departments in the case useful, do not apply to an individual being tested anonymously in a forum linked to the Department or local health departments.

Section 27.2. Reportable diseases.

As proposed, this section would have added the diseases, infections and conditions addressed in these regulations to the general list of reportable diseases, infections and conditions in that section. The Department, at ___ Pa. B. ___ (January 26, 2002) removed that general list from §27.2. These regulations require no amendment to that section as it now reads. The addition to the list of diseases, infections and conditions required to be reported within the Commonwealth of the four reportable matters addressed in this rulemaking is accomplished by amending §§27.21a (relating to reporting of health care practitioners and facilities), 27.22 (relating to reporting by clinical laboratories) and 27.32a (relating to reporting AIDS, HIV, CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV).

Section 27.21a was not included in the proposed rulemaking relating to HIV reporting (31 Pa. B. 2126 (April 21, 2001)). It is a new regulation added by the January 26, 2002 amendments to Chapter 27. This rulemaking amends that section to accomplish what proposed revisions to §27.2 were intended to accomplish: the inclusion of general reporting requirements relating to HIV, certain CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV, and the clarification of reporting requirements relating to AIDS. More specific requirements for the reporting of those diseases, infections and conditions appear in new §27.32a.

Because the few comments received regarding proposed §27.2 apply to §§27.21a, 27.22 and 27.32a equally, those comments and these three sections will be discussed here.

Comments

Requiring reporting of low CD4 T-lymphocyte counts brings noninfected persons into the HIV/AIDS surveillance system. This could encourage inexperienced providers to use the CD4 T-lymphocyte test as a screening tool.

Requiring the reporting of low CD4 T-lymphocyte counts could cause the Department to contact parents of children with low CD4 T-lymphocyte counts and cause concern when the low count could be for a reason other than HIV or AIDS.

Reporting low CD4 T-lymphocyte counts, including results for persons who do not have HIV or AIDS, is burdensome for oncologists and other physicians who care for cancer patients. It is unclear what the Department intends to do with this information, when it relates to cancer patients. Will it be referred to the Cancer Registry?

Response

The Department has not changed the regulations in response to these comments. CD4 T-lymphocyte counts of less than 200 cells/*u*L or of less than 14% of total lymphocytes, without other AIDS-defining illnesses, is an AIDS-defining condition in HIV positive persons. It is also an indication of severe immunosuppression that places the patient at risk for secondary infections. Low CD4 T-lymphocyte counts have a high "predictive value positive" and are mostly indicative of HIV/AIDS; more than 80% of low CD4 T-lymphocyte count test results are among HIV positive persons. Therefore, it is appropriate to require reporting of low CD4 T-lymphocyte counts. Reporting of low CD4 T-lymphocyte counts is now a standard component of HIV/AIDS reporting practices in many states that require CD4 T-lymphocyte tests to be reported.

The primary exception to this high predictive value is in specialized cancer treatment centers. Prevention of unnecessary reporting from such centers will be handled administratively by exempting specific facilities or clinics from reporting CD4 T-lymphocyte results based on documented results of audits indicating that that facility's yield of HIV/AIDS cases from CD4 T-lymphocyte results is low. In addition, it is the Department's public health responsibility to monitor trends of potential adverse public

health outcomes from the population of vulnerable persons with severe immunosuppression regardless of HIV status. The Department will destroy reports of low CD4 T-lymphocyte results that it determines do not coincide with the presence of HIV.

Further, the Department will not send to the Caner Registry information on cases reported because of the CD4 T-lymphocyte reporting requirement. The Cancer Registry is static. The Department does not undertake active cancer surveillance, nor does it track the impact of courses of treatment, as it does through HIV and AIDS reporting. Therefore, information relating to changing CD4 T-lymphocyte counts is not useful with respect to cancer cases.

Comment

All CD4 T-lymphocyte counts should be reportable, and not just those under 200 cells/*u*L or 14% of all T-lymphocytes.

Response

The Department has not changed the regulations in response to this comment. The Department has followed the CDC guidelines in the promulgation of the requirement that CD4 T-lymphocyte cell counts of equal to or less than 200, or 14% of total lymphocytes be reported. The Department is using CD4 T-lymphocyte counts as a marker for HIV disease counts over the limits the Department has included in the regulations would not

be an accurate indicator for HIV. They could be indicative of too many other infections and conditions to be useful as an HIV marker.

Section 27.21. Reserved.

This section has also changed from proposed to final rulemaking based upon the January 26, 2002 amendments to Chapter 27. The Department proposed, in 31 Pa. B. 2126 to delete subsection (e), which required physicians to report cases of AIDS.

In the January 26, 2002 amendments to Chapter 27, however, the Department changed the title and substance of this section to deal solely with the reporting of AIDS by physicians and hospitals. The section had previously dealt with physician duties in reporting all reportable diseases. In this final rulemaking, the Department has consolidated all HIV and AIDS reporting requirements in §27.32(b) (relating to reporting AIDS, HIV, CD4-T lymphocyte counts and perinatal exposure of newborns to HIV). Therefore, the Department has repealed §27.21 in its entirety.

Section 27.22. Reporting of cases by clinical laboratories.

The amendments to this section require laboratories to report the diseases, infections and conditions included in this rulemaking in a particular manner. The amendments to the section also require electronic reporting by laboratories.

The April 21, 2001 proposed amendments to this section were made obsolete by the January 26, 2002 amendments. Consequently, Annex A shows the current amendments

to this regulation as the regulation read after January 26, 2002. Subsection (a) is amended to add the types of testing information that is reportable. This is language that was deleted from the regulations in the January 26, 2002 amendments. The word "examination" replaces the word "test," as a more accurate term. Subsection (b) is amended to require the reporting of HIV test results and low CD4 T-lymphocyte counts.

However, this section does not contain comprehensive standards for those reports. Those standards are provided in new §27.32a. For this reason, subsection (c) is amended to state that the reporting requirements of that subsection apply unless otherwise provided for in Chapter 27. Subsection (d) is amended to require that all laboratory results be reported to the Bureau of Epidemiology electronically in a manner specified by the Department, except for those diseases, infections and conditions which are contained in specific reporting requirements. These include HIV test results and CD4 T-lymphocyte test results.

Because part of the subject matter of proposed subsection (e) is deleted, and the remainder combined with subsection (d), the remaining subsections have been renumbered.

Since all of the comments received by the Department on this section were related to the proposed reporting requirements, the Department has chosen to discuss them under §27.32a, rather than here.

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

The Department has made a minor revision to this section to clarify that persons other than physicians and hospitals are not required to report cases of AIDS, and that only those individuals and entities required by §27.32a are required to report CD4 T-lymphocyte test results as defined by §27.21a, HIV test results or perinatal exposure of a newborn to HIV.

Section 27.32a. **Reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV.**

This section identifies those types of persons and entities required to report the four diseases, infections and conditions included in this rulemaking, and specifies the manner by which the reporting is to be done. Section 27.32, which had been captioned "Reporting AIDS," was repealed by the January 26, 2002 amendments. The subject matter that had been addressed in that section, as expanded to include the three other reportable items added by these amendments, is now addressed in this section.

Subsection (a). *Reporting by clinical laboratories.*

The Department has moved the proposed language relating to reporting by laboratories of HIV test results and CD4 T-lymphocyte counts from proposed §27.22 (relating to reporting by clinical laboratories) to this subsection. The Department has added a reference to section 27.22(b) (relating to reporting of cases by clinical laboratories) to subsection (a) to clarify that laboratories are not required to report all CD4 T-lymphocite case results, but only those that meet the definition included in section 27.22(b).

Comment

If a patient has more than one specimen sent to a laboratory for successive HIV tests, will the laboratory have to report each time the test was positive?

Response

A laboratory is required to report each time a test that establishes the presence of HIV is positive. A laboratory is not required to report preliminary tests for HIV that are not approved by the FDA as establishing the presence of HIV.

Comment

If a patient changes insurance, a new laboratory may have to report the patient. The multiple reports may create problems with confidentiality.

Response

Each test result that meets the standards in paragraphs (1) or (2) must be reported. The Department will review the test results, and develop a single case record, as it does with all other reportable diseases, infections and conditions. Rather than having reporters self-censor, leading to possible under-reporting, the Department prefers to follow the National standard for reporting, and require reporting by all reporters of all reportable results. If a report were not made, the Department would be unable to verify the case or respond appropriately. Confidentiality is not compromised by multiple reports of the same case. The steps that will be taken to safeguard confidentiality will be triggered by each report.

Comment

Requiring laboratories to report is burdensome and invasive of patients' privacy.

Response

The Department has not changed this regulation in response to this comment. This regulation has been developed to provide the Department with the most complete amount of relevant information available on a patient reportable under the regulation. This will help the Department identify every possible case of HIV, and act in a timely and effective manner when appropriate. To best ensure that a case is not missed, and that all important information is collected, the Department is requiring reporting from all possible reporters.

Further, the law directs the Department to require reporting for the protection of the public health. The General Assembly has already balanced the issue of total privacy of the individual against the public health and the health of the individual, and has determined that individual's complete privacy is subordinate to the Commonwealth's compelling need for protection of the public health through reporting of disease and condition information to the Department and the local health departments to facilitate epidemiological understanding and public health interventions. (See the Disease Prevention and Control Law of 1955 (35 P.S. §§521.1-521.21) (the act). The act prohibits the departments from releasing this information to any other person, except under very limited conditions.

Comment

Cases must be reported both to the State and to the local health departments. Both providers and laboratories are being required to report. The Department should either require such dual reporting be done only for new, previously unreported cases, or must financially support the increased reporting requirements.

Response

Providers report only to LMROs; laboratories report only to the Department. The Department will provide the laboratory results to the LMROs electronically. The reasons for requiring multiple reports by multiple reporters have already been fully discussed. Further, the Department does not require repeated reports of a case by a provider who has previously reported the case. Each test that results in a CD4 T-lymphocyte count reportable under these regulations must be reported, however, regardless of whether the case has been previously reported, and will be used to assist the Department in evaluating the progression of disease.

Comment

The Department should include language in proposed §27.22 (c)(2) (adopted as §27.32(a)) exempting laboratories located within Philadelphia from reporting the names and addresses, including city, county and zip code, to the State Health Department. Laboratories would still be required to report this information to the Philadelphia Department of Health.

Response

The Department has not changed its regulations based on this comment. The Department has already discussed its reasons for adopting reporting by name, rather than by unique identifier. The Department sees no reason to exempt laboratories within Philadelphia from this reporting requirement.

Comments

The Department should change the reference to name and address of the person from whom the specimen was obtained in proposed §27.22(c)(1) (adopted as §27.32a(a)(3)(i)) to the person's unique identifier.

The Department should change the reference to date of birth in proposed §27.22(c)(2)(iii) (adopted as §27.32(a)(3)(iii)) to year of birth.

Response

The Department has not changed this regulation in response to these comments. As has already been discussed, the Department has decided against the use of a unique identifier in favor of confidential name-based reporting.

Comment

The Department should delete proposed §27.22(c)(2)(ix), which would specifically require reporting of CD4 T-lymphocyte test results with a count of less than 200 cells/*u*L or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes. This

subparagraph duplicates proposed §27.22(c)(2)(viii), which would require reporting of test results.

Response

The Department agrees, and has not included the substance of proposed §27.22(c)(2)(ix) in this section. Sections 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) identify the CD4 T-lymphocyte results that are reportable.

Comment

Does the requirement that reports be made to the Department within 5 days of obtaining the test results, found in proposed §27.22(d)(4) and (5) (adopted as §27.32a(a)(1) and (2)) afford a laboratory sufficient time to report?

Response

The Department has not changed the regulation in response to this comment. Five days affords a laboratory sufficient time to report. The Department's current experience with laboratory reporting for other reportable diseases, infections and conditions shows that laboratories are capable of reporting within this time frame.

Comment

The Department should delete the word "positive" from proposed §27.22(d)(5) (adopted as §27.32a(a)(2)) in proposed §27.2 (relating to reportable diseases) (now deleted) and in

proposed §27.32a(a)(2) (adopted as §27.32a(b)(1)(ii)). Those regulations require reporting of "the positive results of any test approved by the FDA to establish the presence of HIV including serologic, virologic, nucleic acid (RNA or DNA) or any other type of test . . . ." This should be changed because many of these tests provide neither a positive nor a negative, but rather provide points on a continuum. An example of this is a CD4 assay.

Response

The Department has not changed the regulations in response to this comment. The use of the word "positive" is appropriate as it relates to the definitions for each condition. If the test result meets the definition for a condition, the test result is "positive."

Subsection (b). *Reporting by physicians, hospitals, persons or entities, who diagnose AIDS within the scope of their practice or who receive or provide HIV and CD4 T-lymphocyte test results.*

The proposed amendment of now repealed proposed §27.32 is adopted in subsection (b). Subsection (b) contains direction as to where, how and when reports are to be submitted by a physician, hospital, person providing HIV services or person in charge of an entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV or CD4 T-lymphocyte test results or provides HIV or CD4 T-lymphocyte test results to patients. Subsection (b) requires that reports made by the individuals and entities referenced in the subsection are to be made to the LMRO where the case was tested or has been diagnosed. The comments relating to proposed §27.32 are addressed under this subsection.

Comments

The Department should delineate who is required to report under this regulation. The section as proposed appears broad and vague. It does not appear to meet the intent of the preamble, which stated that the Department intended to capture entities that do not have physicians, but receive test results. Nothing in this section excludes laboratories, and persons within laboratories could be covered by it. The fact that there is no definition of "HIV services" adds to the confusion.

This regulation should address to whom data is to be transmitted. The proposal suggests that it go to the county health departments, when in most counties it would be transmitted to the regional district office of the Department.

Response

The Department dose not agree that this subsection is overbroad or vague. The Department did intend to require reports from all entities that do not have physicians, but who receive or provide HIV and CD4 T-lymphocyte test results. This subsection only requires those entities and persons to file case reports if they also provide HIV services. The Department does agree, however, that a definition of "HIV services" would clarify this section further. The Department has added that definition to §27.1 (relating to definitions). The definition encompasses prevention, treatment and case management services, to ensure that the widest reporting is available to the Department. This definition eliminates a laboratory's duty to report from this subsection. Subsection (a), which is specifically directed to laboratories, does not make a laboratory subject to the

requirement that it also provide HIV services. The substance of subsection (a) does not differ from what the Department proposed in §27.22(d).

With respect to the issue of where reports are to be made, the regulation clearly states that providers are to report to the LMRO where the case has been diagnosed or is located. An LMRO includes, by definition, the county and local health departments. There is no confusion about where laboratories are to report, since subsection (a) explains where, how and when laboratory reporting is to occur.

Comment

The regulations should specify who is responsible to report HIV for an entity that provides HIV services. Section 27.22 states that a person who is in charge of a laboratory is required to report. Similar language should be added here.

Response

The Department agrees, and has added to subsection (b)(1) "person in charge" language similar to that in §27.22.

Comment

Dentists should not have an HIV or AIDS reporting responsibility since a dentist does not diagnose or treat HIV or AIDS. The information that a dentist may have relating to HIV or AIDS is provided by a physician, a laboratory, or an infected patient.

Response

A dentist providing dental services to a client with HIV is no different than a dentist providing services to any other client with a communicable disease. A dentist operating in that capacity does not need to report HIV. Should the dentist have occasion to provide HIV services, as defined in the regulations, and receive or provide HIV test results, that dentist would be required to report.

Comment

Proposed amendments to §27.32 (adopted as subsection (b) of this regulation) duplicate some of the reporting requirements in §§27.21 (relating to physicians who treat patients with reportable diseases including tuberculosis), 27.23 (relating to school reports of communicable diseases), 27.24 (relating to reports by heads of institution) and 27.25 (relating to reports by other licensed health practitioners). The Department should amend those existing sections of the regulations, rather than adopt a new regulation, to include new reporting requirements applicable to entties with reporting responsibilities subject to the aforementioned regulations.

Response

The Department has not changed the regulations in response to this comment. The Department repealed §§27.24 and 27.25 when it amended its regulations on January 26, 2002. At that time, it also amended §27.23. That section, which previously related to only school reports of communicable diseases, was amended to include reporting requirements for persons other than health care practitioners, facilities, laboratories or veterinarians. Because only certain persons are required to report HIV and AIDS,

amending §27.23 to require HIV or AIDS reporting would not be appropriate. Further, the Department, in keeping with the January 26, 2002 amendments, has placed specific requirements relating to HIV and AIDS reporting in that part of Chapter 27 that includes sections relating to diseases and conditions requiring special reporting. Section 27.21 is repealed by this rulemaking. The subject matter that had been addressed in §27.21 is now included in this subsection.

Comments

The Department's requirement that entities receiving test results report to the Department means that entities that receive test results are required to make diagnoses. Only clinicians should be required to make a diagnosis. Laboratories should not be required to report without a diagnosis.

The Department should clarify that only physicians can diagnose. As written, §27.32(a) (adopted as subsection (b) of this regulation) links hospital, person, or entity providing HIV services to the words "makes a diagnosis," and this causes confusion.

Response

The Department has not changed the regulation in response to these comments. The regulations do not require anyone to make a diagnosis of AIDS, nor do they require any practitioner to exceed the scope of the practitioner's practice. The regulations simply require that if a person makes a diagnosis of AIDS, that diagnosis must be reported. It is the Department's assumption that a person not authorized to diagnose within the scope of

his practice will not do so. Further, the Department is not requiring entities or persons receiving the designated test results to make diagnoses, but is requiring them to report those test results. Test results are empirical data. That data can be reported without the person making a clinical decision or diagnosis.

Comment

Requiring reporting of case management agencies is burdensome and invasive of a patient's privacy.

Response

The Department has not changed this regulation in response to this comment. This regulation has been developed to provide the Department with the fullest amount of relevant information available on a patient reportable under the regulation. This will help the Department identify every possible case of HIV, and act in a timely and effective manner when appropriate. To best ensure that a case is not missed, and that all important information is collected, the Department is requiring reporting from all possible reporters.

Further, the law directs the Department to require reporting for the protection of the public health. The General Assembly has already balanced the issue of total privacy of the individual against the public health and the health of the individual, and has determined that individual's complete privacy is subordinate to the Commonwealth's compelling need for protection of the public health through reporting of disease and condition information to the Department and the local health departments to facilitate

epidemiological understanding and public health interventions. (See the Disease Prevention and Control Act of 1955 (35 P.S. §§521.1-521.21). The act prohibits the departments from releasing this information to any other person, except under very limited conditions.

Comment

The Department should add the words "or is diagnosed within" to proposed §27.32 (a), following the words "when the individual who is a subject of the report is a resident."

Response

The commentator misunderstood the proposal. The Department had proposed to repeal §27.32(a) as it read at the time the proposals were made. The language referred to by the commentator is not included in §27.32a(b).

Comment

Proposed §27.32(a) (adopted as subsection (b)(1) of this section) would require that a report be made to the LMRO where the patient is diagnosed or tested. The Department is to be commended for including this language and changing its requirement that reports are to be made to the LMRO where the patient resides. The Department should make this change in all its disease regulations.

Response

The Department agrees that this should be the general reporting standard. In addition to retaining that language here, it has added similar language to its general regulations relating to communicable and noncommunicable disease reporting in §27.4 (relating to reporting cases).

Comment

The Department should change the reference in proposed §27.32(a)(4) (adopted as subsection (b)(4)(iv) of this section) from "perinatal exposure" to "vertical transmission."

Response

The Department has not changed the regulation in response to this comment, for the reasons cited in its response to comments on the definition of "perinatal exposure of a newborn to HIV" in §27.1 (relating to definitions).

Comments

The Department should clarify what it means by "perinatal reporting." Will all newborns be tested? How will confidentiality be assured throughout the follow-up process?

There is a possibility of testing pregnant women. How will this be managed, and will confidentiality be ensured throughout any follow-up process?

Response

The Department has not changed the regulation in response to these comments. The Department is not requiring testing of newborns or pregnant women. The regulation requires a report of the exposure of the newborn to HIV. The Department has recommended that pregnant women be tested, through dissemination of CDC guidelines for reducing perinatal exposure. The Department will work with the provider to ensure that the mother is properly counseled and has the opportunity to receive treatment that would reduce the risk of transmission. Again, the Department will only become involved with the case upon invitation by the provider, although the Department may contact a provider, advise of the services the Department can provide, and ask whether Department assistance is desired. The provider does not breach confidentiality or the patient-physician relationship by reporting in accordance with the regulations, since the reporting of patient information required by these regulations is a statutorily authorized exception to patient privacy.

Comment

Children exposed to HIV during pregnancy will be tracked by name, even if they are uninfected. There is no provision for removing from the database the names of those children who are shown not to be HIV-positive by a negative confirmatory test. This should be included in the regulations.

Response

The Department has not changed the regulation in response to this comment. Children who are not HIV-positive will not be a part of the HIV database. The names of children perinatally exposed to HIV will be maintained as part of the perinatal exposure database. The Department's retention of the names of children not found to be HIV-positive after birth is to allow the Department to perform follow-up for several reasons.
Requiring reporting of the perinatal exposure of newborns to HIV will 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 will 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.

Further, maintaining a list of children potentially exposed but not actually HIV positive will allow the Department to track certain treatments used in attempting to prevent the transmission of the infection, as has already been discussed.

Comment

The regulations should require a report of counseling given regarding treatment/prophylaxis, mode of prophylaxis chosen or denied and why, mode of delivery,

and other indicators of efforts made to prevent vertical transmission. This would be useful in ensuring that best practices are in place and are utilized, when in the judgment of the woman, treatment is in her interest and those of the unborn child.

Response

The Department agrees that the question in the case report form that elicits information on prevention and care service referrals should be expanded. This will enable the Department to collect more useful information. The Department is taking steps to make that change to the form, but sees no need to revise subsection (b) to do so.

Comment

The Department should strike the language "in a timely manner" from §27.32(b) and replace it with a period of time consistent with the period of time in which other providers are required to report.

Response

The commentator misunderstood the proposal. The Department had proposed to repeal §27.32(b) as it read at the time the proposals were made. The language referred to by the commentator is not included in §27.32a(b).

Comments

The Department should remove references to the name of the individual from proposed §27.32(b) (adopted as subsection (b)(2)(i) of this section) and replace it with a unique identifier.

The Department should add language stating that Philadelphia County will substitute an identifier for the patient's name and street address as required in proposed §27.32(b)(1) (adopted as subsection (b)(2)(i) of this section) for reports of positive HIV test results.

Response

The Department has not changed the regulation in response to these comments. The Department has decided to use a system of name-reporting for the reasons previously discussed in this preamble. This reporting system will work the best for the Commonwealth if it is used throughout the Commonwealth.

Comment

Proposed §27.32(b)(8) and (9) duplicate the list of diseases in proposed §27.32(a) (adopted as subsection (b) of this section) and should be deleted.

Response

The Department has deleted the language, and replaced it with a requirement that the test results be reported. (See subsection (b)(2)(viii)).

Comments

The language "probable mode of transmission" in proposed §27.32(b)(10) (adopted as subsection (b)(2)(ix) of this section) requires a subjective assessment. This opens the door for judgments about the individual. Providers should be instructed to use only those categories of risk delineated by the CDC.

Rather than use the term "probable mode of transmission" the Department should use the exact language requesting the information used by the CDC report form on which the Department plans to collect this data.

Response

For purposes of clarification, the Department has changed the language. Subsection (b)(2)(ix) requires the patient's history on probable modes of transmission. The Department's reporting form is the CDC form, and the information the Department is soliciting are those categories of risk delineated by the CDC. Patient history information that is entered on the case report is essentially factual information elicited through patient interviews and counseling on the likely modes of transmission. This is documented in the patient chart or the counselor's notes and is not based on subjective judgments. As reported cases may often have multiple risks or exposures, the CDC data management software objectively assigns the patient's risk index for most likely/most probable mode of transmission using a hierarchical risk assignment algorithm based on a scientifically established hierarchy of relative risks for the various modes of transmission listed on the

CDC report form. The phrase "patient history on probable modes of transmission" is therefore more descriptive of the information the Department intends to capture.

Comment

Unless the Department can specifically list what other information it would deem to be relevant, proposed §27.32(b)(14) (included as subsection (b)(2)(xiii) of this section) which requires reporting of any other relevant information required by the Department, should be deleted.

Response

The Department agrees with the comment, and has deleted subsection (b)(2)(xiii).

Comment

The time line given for reporters to report in proposed §27.32(c) is too short, given the amount of information expected. This is especially true for physicians, unless the Department expects reporting to be done before the clients are given post-test counseling as required by law. This would mean reports would be required before patients could be notified personally.

Response

The Department has not changed the regulation in response to this comment. The Department is requiring in subsection (b)(1) that the report be made within 5 days after the person subject to subsection (b) makes the diagnosis or receives the test result. This

provides ample time for the physician or counselor to discuss the matter with the patient. In any event, the Department will not be making any contact with a patient without a request from or referral by the provider. Therefore, the Department will have no contact with the patient unless the provider determines that contact would be useful for the patient. The only exception would be in the event of a public health emergency or outbreak, which would require that the Department act expeditiously to prevent and control the spread of disease, an unlikely scenario with respect to HIV or AIDS.

Comment

In proposed §27.32(c) (adopted as subsection (b)(3) of this section) the Department is requiring providers to maintain information in the patient's file. The Department should clarify what is meant by "the patient file." Is this to be electronic or on paper? Can the information be maintained in the disease report files, or must it be maintained in the patient's medical record?

Response

The Department has not changed the regulation in response to this comment. See subsection (b)(3). The Department intends the information to be maintained in the patient's medical record. The Department does not intend to specify the method by which that record is to be maintained.

Section 27.32b. Confidential and anonymous testing.

This section had been proposed as new §27.32a. It is being renumbered for the reason previously discussed. It permits anonymous testing at certain sites designated by the Department as anonymous HIV testing sites, and includes requirements for reporting by those sites. It also prohibits anonymous testing at any other site unless it is conducting blinded HIV testing authorized under section 5(f) of Act 148 (35 P.S. §7605(f)).

Several commentators supported the Department's intention to continue to allow anonymous testing sites within the Commonwealth, since anonymous HIV testing provides a testing option for those who would otherwise refuse to be tested.

Comments

The mechanisms for State designation of anonymous testing sites are unclear.

The Department should explain how anonymous testing sites are to be chosen. Planned Parenthood has worked tirelessly to build relationships with its clients. If the Department does not permit these sites to continue as anonymous testing sites, the Department will lose this data, since name-based reporting is likely to deter persons who would have been tested at these sites from being tested. The regulations should allow for sites currently providing anonymous testing to continue to do so.

In Bucks County, 5 Planned Parenthood sites and the county health department are the only sites at which anonymous testing are occurring. The hours at the county health department are inconvenient to young persons who work or are in school. The

Department should make provisions in the regulations for sites currently providing anonymous testing to continue to do so.

The Department should ensure adequate numbers of anonymous testing sites. It is advisable to have one or more test sites per county.

The regulation does not define "State-designated," or indicate whether sites that are now providing anonymous testing will be "State-designated."

Response

To clarify the meaning and criteria applicable to anonymous and confidential testing, and State-designated HIV-testing sites, the Department has added definitions for these terms (see §27.1 (relating to definitions)), and has removed redundant language from this section. While the Department will not automatically accept any site currently performing anonymous HIV-testing as a State-designated site, all Department-supported HIV counseling and testing sites will remain State-designated anonymous HIV testing sites. In addition, the Department may choose to designate and fund additional anonymous HIV-testing sites if the Department finds, based on information reported to it under the Communicable Disease Regulations, that individuals are having problems accessing anonymous testing in a specific area. The Department may either ask a provider to provide anonymous testing, or agree to a request from a provider where the same circumstances exist. A State-designated site must accept the Department's standards which are based on the CDC guidelines for the provision of HIV testing,

counseling, referral and partner notification and the Department may choose to grant that provider the funds to carry out the services. The CDC guidelines are available from the Department.

Anonymous HIV-testing sites may also provide confidential testing.

The number of anonymous test sites is over 130, located throughout the Commonwealth. These include the Department's state health centers, local health departments, and sites operated by publicly funded providers. This number fluctuates because of the constant addition and deletion of sites due to changes in these agencies and the turn-over of qualified counseling staff. The six county (Philadelphia, Allegheny, Bucks, Montgomery, Chester, and Erie) and four municipal (Allentown, Bethlehem, York, Wilkes-Barre) health departments were also asked by the Department to choose the number and location of sites to be designated as anonymous HIV-testing sites in each of their health jurisdictions. The Department did not limit the number of anonymous sites each of the county and municipal health departments were permitted to choose.

Further, the Department's regulations do not prohibit persons who operate State-designated anonymous HIV-testing sites from providing services in places where they have no physical facility. Once a site is designated by the Department, that site's operator can, and several do, send the site's workers into other communities where it has no physical facility to perform outreach and testing. The Department's regulations do not prohibit this type of outreach.

Comment

The number and distribution of anonymous HIV-testing sites may be inadequate, particularly in rural areas. The Department's regulations limit anonymous testing sites to those designated by the Department, limiting an already small number of sites. Although the Department has stated there are over 100 such testing sites, most of these sites offer both confidential and anonymous testing. There are only 10 true anonymous testing sites available. Limiting anonymous testing sites will deter persons from being tested. The Department should make a commitment in the regulations to increase access to anonymous testing and expand the number of anonymous HIV-testing sites.

Response

It is not the intention of the Department to limit access to anonymous HIV testing. It is also not correct that there are only 10 true anonymous testing sites available. The Department has approximately 126 anonymous testing sites. The number of anonymous sites will fluctuate because of the constant additions and deletions of sites due to changes in contracted agencies and turnover of qualified counseling staff. All State-designated sites will provide anonymous testing if requested.

Comment

The regulations should require confidential testing sites to provide an explanation to the client that anonymous testing is available.

Response

While anonymous HIV-testing sites also provide confidential testing, the choice is up to the individual being tested. In the course of pre-test counseling at State-designated anonymous HIV-testing sites, the individual is advised that he may choose to be tested confidentially or anonymously at that site. The Department supports other providers making persons aware of the possibilities of both anonymous and confidential testing, and referring them to anonymous HIV-testing sites, but will not require it. The Department is concerned that if a provider was required to offer anonymous testing to a a person coming to that provider for treatment or services other than HIV services, the provider could then find it necessary to refer the person to another site, and valuable treatment opportunities could be lost. For example, a person referred from an STD clinic to another site for anonymous HIV-testing might assume that the anonymous testing site could treat all his problems. He could fail to obtain necessary STD services, since those anonymous HIV-testing sites might not have the capability to treat STD.

Comment

The availability, location and hours of anonymous HIV-testing sites should be clearly established and publicized prior to the institution of these regulations.

Response

The regulations will be effective 90 days after publication. The Department will post lists of State-designated anonymous HIV-testing sites on its website, including the days and hours of operation of each during this 90-day period.

Comment

The regulations should make reference to periodic audits that will ensure anonymous testing is available to all Pennsylvania citizens throughout the Commonwealth.

Response

The Department has not changed the regulation in response to this comment. The Department will maintain quality control of the State-designated anonymous HIV testing sites in a manner that is consistent with the need to ensure the quality of patient care. The Department will also monitor the sites to ensure that anonymous HIV-testing is actually available at those sites.

Comment

Anonymous testing should not be permitted at only State-designated sites. Anonymous testing should be the standard procedure throughout the Commonwealth.

Response

The Department has already discussed its reasons for choosing to promote confidential name reporting as its primary mechanism for receiving HIV case reports.

Comment

The Department should add the following language:

> Anonymous testing for HIV in Philadelphia will be provided at those sites designated by the local health authority. Anonymous testing in Philadelphia is testing provided to an individual without collecting the name or any other information that could be used to ID an individual (street address, or algorithms based all or in part on the individual's name, social security number, date of birth). Confidential HIV testing in Philadelphia will require that the name of the individual tested be collected and reported to the local health authority upon receipt of reportable test results. Case reports on reportable HIV results obtained from all but anonymous test sites will be reported to the State substituting a UI for the name of the individual for whom a reportable HIV test result was obtained.

The Department should add the following language:

> Philadelphia will report anonymous HIV test results without identifiers, utilizing the case identification number to differentiate case reports.

Response

The Department has not changed the regulation in response to this comment. The Department has decided to use a system of name reporting for reasons previously discussed in this preamble. This reporting system will work best for the Commonwealth if it is used throughout the Commonwealth.

Comment

The Department should delete the language from subsection (a) that states "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." The language is confusing, and seems to indicate that anonymous providers must report confidentially.

Response

The Department agrees that the section should be clarified, although it has not deleted the language in response to this comment. The Department has added, at the end of that sentence, the last sentence of subsection (a), the phrase "unless it is a State-designated anonymous HIV-testing site." This language reinforces the Department's requirement that only State-designated testing sites may perform anonymous testing.

Comments

The Department appears to be negating the intent of anonymous HIV testing by requiring the reporting of addresses and dates of birth. Unless two persons are twins and live together, this can hardly be considered to be anonymous HIV testing.

If anonymous testing sites report the information as the regulations require, how does the test remain anonymous? Does the Department intend to include certain categories of information from proposed §27.32? Why is this information, date of birth, address, sex, race, required in an anonymous test?

Response

The Department has revised subsection (b) to clarify that the Department is not requiring the reporting of addresses, social security numbers, and other potentially identifying data on individuals for whom an anonymous test was conducted. The data collected will be the information listed in §27.32a(b)(2), except for name and address, which is information useful for the public health purpose of assessing whether targeted high risk populations are being reached by counseling and testing. The Department has also changed the regulation to clarify that a preprinted number on the Department's HIV Counseling and Referral Form will be reported in lieu of the information required in §27.32a(b)(2)(i), with the exception of the individual's county of residence. An algorithm will not be used.

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

This section had been proposed as new §27.32b. It is being renumbered for the reason previously discussed. It states that counseling, testing, referral and partner notification must be done in accordance with Act 148. It also states that a person providing HIV test results to a patient may ask for the Department's assistance in doing so.

Comment

The language that states that persons may ask the Department's assistance if to do so would not violate Act 148 seems to suggest that the regulation supersedes the statute. This is not legally permissible.

Response

This section is included in the regulations so that the requirements of Act 148 would be considered by providers and acted upon. Act 148, however, provides that information may be released to the Department without consent as authorized by the act. Since the act gives the Department the authority to require reporting of HIV through the promulgation of regulations, as the Department has now done, information may be shared with the Department for purposes of post-test counseling without violating Act 148. Therefore, the language that states the Department's assistance may only be sought if Act 148 permits it is unnecessary, and the Department has deleted it.

Comments

The Department should clarify how follow-up of HIV infected persons will occur under a system of name reporting, and how confidentiality will be affected or improved. How will partner notification be handled?

We are concerned about how confidentiality will be protected during follow-up. We have had success in convincing the client to bring partners in when there is a diagnosis of STD or a potential for HIV infection. Partner notification will be complicated by name-reporting.

Response

The Department currently performs partner notification or, as it is now referred to, partner counseling and referral services (PCRS), and has done so for some time. PCRS has two goals: first, to provide counseling and testing services to sex and needle sharing partners of HIV infected persons so they can avoid infection or, if they are already infected, to prevent transmission to others; and second, to help partners gain earlier access to HIV counseling, testing, medical evaluation, treatment and other prevention services. These could include, for example, STD treatment, drug treatment, violence prevention, social support, family planning and housing.

The agreement to participate in PCRS is voluntary on the part of the HIV infected person. In PCRS, the infected person is encouraged to voluntarily and confidentially disclose the identifying, locating and exposure information for each sex or needle-sharing partner that the Department or the infected person will attempt to inform. During PCRS, information

about the infected person is never revealed to the partner; this includes the person's name, sex, and physical description, or time, type, or frequency of exposure the partner may have had with the infected person.

During HIV prevention counseling, the rationale and options for PCRS are explained by the counselor. The counselor assists the HIV infected person in understanding the person's responsibility for ensuring the person's partners are informed of their possible exposure and for referring those partners to HIV prevention counseling, testing and other support services. The prevention counselor counsels the person on if, how and when specific partners should be informed of their risk of exposure. The options for PCRS are discussed and a plan for notifying each partner is developed. Options for PCRS include: client referral, in which the HIV infected person informs the person's partners and refers them to HIV counseling and testing services; provider referral, in which the provider informs the person's partners and provides the HIV counseling and testing; or dual or combined referral, in which both the infected person and the provider together inform the person's partners.

PCRS personnel never reveal to the individual's friends, relatives or neighbors why they are trying to find a person. They never leave a note or message that mentions HIV exposure as the reason for attempting to make contact. No information is revealed that might lead others to learn the reason for the attempted contact or that might otherwise lead to disclosure of sensitive information or to a breach of confidentiality. When the Department is involved in the partner notification process, all partners are informed of

their possible exposure to HIV privately and face-to-face. If the partner refuses to meet with the provider, a telephone call might become necessary, but only limited information is provided to the partner over the phone, with the ultimate goal of arranging a face-to-face meeting.

Name reporting should not have an impact on this system. Partners must agree to be tested, and the fact that they choose to meet with a provider does not mean that testing occurs. Once the anonymous and confidential HIV testing options are explained to them, in the Department's experience, most partners opt for confidential HIV testing.

Section 27.32d. Department authority to require complete reporting.

This section had been proposed as new §37.32c, rather than §27.32c, as a result of a typographical error. It is being renumbered for the reason previously discussed. It reiterates the Department's authority, contained in the act, to make complete investigations of communicable and noncommunicable diseases, infections and conditions, including outbreaks. This includes the Department's authority to review records of reporters as necessary.

Comment

The section is unclear and should be broken into two sentences.

Response

The Department has made the change suggested.

Comment

Although the Department's need for the information is understood, the Department did not implement the HIV regulations in a timely fashion. The Department should work with physicians and hospitals to develop the most effective and least disruptive means of collecting needed information. This same comment is applicable to §27.32e (relating to record audits.

Response

The Department is cognizant of the need for cooperation and education. The Department currently conducts case investigations involving physicians and hospitals, and always attempts to work with those entities to obtain their cooperation. The Department intends to continue that practice.

Comment

The Department should strike out "all other persons or entities providing HIV services" from this section, because only physicians or clinicians can make a diagnosis.

Response

As the Department has stated in its responses to comments on proposed §27.32(a) (adopted as 27.32a(b)), the regulations do not require any person to make a diagnosis. No person should be making a diagnosis other than a person who, within the scope of that person's practice, is authorized to do so.

Section 27.32e. Record audits.

This section had been proposed as new §27.32d. It is being renumbered for the reason previously discussed. It states that the Department will conduct record audits back to January 1, 2000, for the purposes of completing case investigations.

The Department has added the word "to" between the words "chapter" and "ensure" in subsection (b).

Comment

The Department should strike out "all other persons or entities providing HIV services" from subsection (a), because only physicians or clinicians can make a diagnosis.

Response

The Department has not changed the regulation in response to this comment. As the Department has stated in its responses to comments on proposed §27.32(a) (adopted as §27.32a(b)), the regulations do not require any person to make a diagnosis. As the Department has stated, it does not expect any person to make a diagnosis other than a person authorized to do so within the scope of that person's practice. If a diagnosis of AIDS is made, then it must be reported.

Comments

The Department should delete the proposed language stating that it will conduct audits back to January 1, 2000. This could create legal problems for providers, who do not have consents permitting them to release this information. If the individual is in care, he will have periodic tests, which, in the course of a year will cause him to be reported to the Department.

The proposed section violates the physician/patient privilege and ignores the need for patient consent.

Response

The Department has not changed the regulation in response to these comments. The audits will be done to collect information to complete HIV and CD4 T-lymphocyte case reports. The Department is instituting this requirement to allow 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 United States Department of Health and Human Services (HHS). One of the reasons the Department included this section, and §27.32d (relating to Department authority to require complete reporting), is that, in the past, the Department has had difficulty in securing cooperation from some providers. They have refused to allow the Department to review patient records to enable the Department to complete its case report files.

The Department's authority to conduct these record reviews without patient consent is clear in the act. Sections 3 and 5 of the act (35 P.S. §§521.3 and 521.5) 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 (35 P.S. §521.16) gives the Department, through the Board, the ability to promulgate whatever regulations are necessary to prevent and control the spread of disease. Further, section 2102(a) of the Administrative Code of 1929 (71 P.S. §532(a)) gives the Department the authority to take the most efficient and practical means necessary for the prevention and suppression of disease. The reviews permitted by this section are necessary for locating cases of HIV and AIDS and controlling and preventing the spread of disease. Consequently, the Department is authorized by the act to promulgate regulations concerning those reviews, and is not required to obtain patient consent to conduct those reviews. The fact that the information is HIV-related information does not change this provision, since Act 148 includes an exception that allows the information to be provided to the departments for the purpose of disease control and prevention. (See 35 P.S. §7607(a)).

Further, since section 4 of the Act (35 P.S. §521.4) places reporting responsibilities on certain persons, and section 16(a) and (b) of the act (35 P.S. §521.16(a) and (b)) give 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. The regulation, therefore, clearly states the

Department's authority to conduct these types of reviews of patient records. This should eliminate the occasional lack of cooperation on the part of providers.

Comment

The Department should not limit its ability or the ability of local health departments to obtain information by placing a time limitation on its back auditing. It should delete from subsection (a) the reference to January 1, 2000.

Response

In considering the interests of providers as well as the need for information, the Department has determined that reviewing information back to January 1, 2000, will sufficiently serve its purpose.

Comment

What are the "special reports" referenced by the Department in subsection (b)?

Response

By the term "special reports," the Department means reports that are not specifically disease reports, but, rather, are intended to help the Department prevent, track, and control the spread of disease in a particular situation, or that will enable the Department to monitor reporting practices. For example, several years ago, the Department received reports of needle stick injuries in a particular county, caused by adolescents surreptitiously sticking other persons with needles, and raising concern of potential

exposures to blood borne diseases. The Department requested that the provider who initially made the report respond to a report form developed by the Department with regard to these specific incidents, including a time line and other questions relating to the potential exposures.

As another example, the Department could request that certain providers respond to a given set of ICD-9 codes with a listing of all cases matching those codes, and the dates, if any, that the case was reported to the Department. This would enable the Department to determine if reporting by those specific providers was complete.

Several commentators made general comments that were not associated with any section or regulatory provision.

Comments

The effective date is unrealistic, given the publicity and training that needs to be accomplished.

It will be hard for reporters to be prepared to report by January 1, 2002. There will be limited staff available to implement these requirements. The Department should adjust implementation accordingly.

Response

The Department has changed the regulation. The Department had originally proposed a January 1, 2002 implementation date for reporting; however, the promulgation of these regulations was dependent upon the promulgation of final rulemaking relating to communicable and noncommunicable diseases. Those regulations were effective on January 26, 2002, therefore, the Department could not keep to the proposed implementation date. The implementation date for reporting will be 90 days after the effective date of these regulations. The Department's operational plan includes time for training and education of providers. The Department is prepared to deal with issues that arise during that phase of the process.

Comment

The use of the term "public health intervention" in the preamble to the proposed regulations is neither defined nor described in regulatory language, and so is open to broad interpretation. Interventions should be specifically designed using best practice models and described in detail in regulatory language. These should only be implemented as a last resort after a clinician has exhausted all other avenues of contacting an individual, not as a first step as the regulations suggest. Community-based organizations should be included in these interventions.

Response

The Department has not changed the regulations in response to this comment. The term "public health intervention" does not appear in the regulations, and only appears in the

preamble to proposed rulemaking in language discussing the Department's reasons for requiring the reporting of low CD4 T-lymphocyte counts that may ultimately prove not to be connected to HIV or AIDS. The Department has not included descriptions of "best practices" for public health interventions in the regulations. Public health practices change with changing science and the development of new and more effective methodologies for preventing and controlling the spread of disease. The Department will not tie itself to practices which might become outmoded. The Department consistently acts within CDC guidelines in carrying out its public health function.

With respect to the manner in which the Department will interact with private providers in the context of HIV cases, the Department has said that it will not directly contact the individual. The Department will use the provider as the point of contact, and will not intervene in the case without offering its services to the infected individual through the auspices of the provider.

Comment

The Department should add a penalty for those reporters who do not report in violation of the regulations. Allegheny County Health Department makes failure to report a summary offense and a civil penalty of up to $300.

Response

The Department has not changed the regulation in response to this comment. This rulemaking is a part of the Department's communicable disease regulations, and is being

promulgated under the act. The act includes the same $300 penalty and summary offense referenced by the commentator for any violation of the act or regulations promulgated under the act. (35 P.S. §521.20). For the Department to impose an additional penalty would require action on the part of the General Assembly.

Comment

The discrepancy between this rulemaking and the rulemaking relating to communicable and noncommunicable diseases will make who is to report AIDS unclear.

Response

The Department has not changed the regulations in response to this comment. There will be no discrepancy in Chapter 27 of the Department's regulations regarding who is to report AIDS. The Department had proposed to delete language from its regulations requiring hospitals to report cases of AIDS. (See 30 Pa. B. 2715 (May 27, 2000)). That deletion was inadvertent. The Department addressed that issue in its final rulemaking published on January 26, 2002. As discussed previously in this preamble, the Department has taken steps to coordinate this rulemaking with the January 26, 2002 amendments to Chapter 27.

C. AFFECTED PERSONS

These regulations 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 are required to report diagnosed cases of AIDS, HIV test results, low CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV. The regulations also affect laboratories, which are required to report certain positive HIV test results and CD4 T-lymphocyte counts of a certain level.

The regulations 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 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. Unless these individuals choose to seek testing at an anonymous testing site (an option not available for pregnant women being tested during or immediately prior to labor because they are most likely in a hospital setting where anonymity is impossible) the names of those persons with these conditions or infected with HIV will be reported to the Department. The required reporting of these conditions and test results permits 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 enables 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 amendments 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 will 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 will be necessary because of the increase in the number of actual cases that should be reported once the reporting of the additional conditions imposed by this rulemaking goes into effect. The Department believes that this increase in cost to the Commonwealth will be outweighed by the savings from these regulations, caused by reporting of information that will enable the Department to focus prevention efforts on the most at-risk populations. Over time these activities will cause a reduction in the number of HIV cases in the Commonwealth. This will reduce health care costs.

No additional cost accrues 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 will 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 creates no measurable increase in paperwork. Cases of HIV, low CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV will 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, free of charge, to those persons required to report. The Department is willing to accept alternative forms of electronic reporting from those who do not have internet access, for example, by accepting reporting by diskette.

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 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 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 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 disease prevention and control measures in those facilities.

F. EFFECTIVENESS/SUNSET DATES

The regulations will become effective upon final publication in the Pennsylvania Bulletin, however, the reporting requirements for positive HIV tests, low CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV will not become effective until 90 days after the final publication of this rulemaking. 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 of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§745.1-745.14), on December 8, 1999, the Department submitted a copy of Notice of Proposed Rulemaking published at 30 Pa. B. 2715 (May 27, 2000) to IRRC and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with section 5(c) of the Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

In compliance with section 5.1(a) of the Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on May 15, 2002. In addition, the Department provided IRRC and the Committees with information pertaining to

commentators and a copy of a detailed regulatory analysis form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

These final-form regulations were approved by the House Health and Human Services Committee on _____ and approved by the Senate Public Health and Human Services Committee on _____. IRRC met on _____ and approved the regulations in accordance with Section 5.1(e) of the Act. The Attorney General approved the regulations on _____.

H. CONTACT PERSON

Questions regarding these regulations may be submitted to Joel H. Hersh, Director, Bureau of Epidemiology, Department of Health, P.O. Box 90, Harrisburg, PA 17108, (717) 783-4677. Persons with disabilities may submit questions in alternative formats such as audio tape, Braille or 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 at the above address or telephone numbers so that necessary arrangements may be made.

I. FINDINGS

The Department, with the approval of the Board, finds that:

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

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

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

J. ORDER

The Department, with the approval of the Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 28 Pa. Code Chapter 27, are hereby amended by repealing §27.21, by amending §§27.1, 27.21a, 27.22, and 27.23, adding §§27.32a, 27.32b, 27.32c, 27.32d and 27.32e, as set forth in Annex A.

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

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

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

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

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-166
SUBJECT:	Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV
AGENCY:	Department of Health #2185 Tolled

TYPE OF REGULATION

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

X Delivery of Tolled Regulation

X a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
5/31/02	J. Chan	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
5/31/02		
5/31/02		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
5/31/02		
5/31/02		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU