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**INDEPENDENT REGULATORY REVIEW COMMISSION**  
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

June 21, 2001

Honorable Robert Zimmerman, Jr., Secretary  
Department of Health  
802 Health and Welfare Building  
Harrisburg, PA 17108

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 Secretary Zimmerman:

Enclosed are our Comments. They will soon be available on our website at [www.irrc.state.pa.us](http://www.irrc.state.pa.us).

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce  
Executive Director  
wbg  
Enclosure

cc: Honorable Dennis M. O'Brien, 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  
Nia Wilson, Legal Counsel, House Health & Human Services Committee  
Stanley Mitchell, Chief Counsel, House Health & Human Services Committee

# **Comments of the Independent Regulatory Review Commission**

**on**

## **Department of Health Regulation No. 10-166**

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

**June 21, 2001**

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Department of Health (Department) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by May 21, 2003, the regulation will be deemed withdrawn.

**1. Identification of the individual by name and address. - Need; Reasonableness; Protection of the public health, safety and welfare.**

Sections 27.22(c)(2)(i) and 27.32(b)(1) require reports to include "The individual's name and the address, city, county and zip code of the individual's residence." Accordingly, the individual would be directly identified in reports to the Department's Bureau of Epidemiology and the Local Morbidity Reporting Office.

The Department claims that confidentiality will not be compromised. The Preamble states "...the confidentiality of the information reported under these proposed regulations will be strictly maintained by the Department and local health departments." The Department also explains in the Preamble that:

- This requirement is consistent with recommendations from the United States Center for Disease Prevention and Control (CDC), and with requirements in 34 other states;
- Confidential name based reporting allows the most accurate tracking of Human Immunodeficiency Virus (HIV) disease and increases the opportunity for intervention; and
- Confidential name based reporting is needed for Pennsylvania to qualify for the highest levels of HIV grant money through the Ryan White Comprehensive AIDS Resources Emergency Act.

We have received extensive comment in favor of and against name based reporting. Senators Harold F. Mowery, Jr. and Timothy F. Murphy, Chairman and Vice Chairman of the Senate Public Health and Welfare Committee (Senate Committee), submitted a joint letter in support of the regulation, including support of name based reporting, as long as sufficient anonymous testing is available.

Representative Dennis M. O'Brien, Chairman of the House Health and Human Services Committee (House Committee) submitted a letter stating the House Committee believes unique identifiers should be used as the means of tracking this epidemic. The House Committee believes the use of names in reporting will deter people from being tested, and hence, infected people may never receive treatment. Senator Vincent Hughes, Minority Chairman of the Senate Committee, expressed similar concerns that "names-based reporting will create an unnecessary risk of both reduced HIV testing and delayed treatment for those Pennsylvanians who are HIV+." Other commentators opposed to reporting the individual's name stated:

- This requirement will deter people from getting tested, and thus compromise treatment and prevention of HIV disease.
- A unique identifier, other than the individual's name and address, can meet all of the requirements and guidelines issued by federal funding agencies.

There are two concerns with including the individual's name and address in a report.

First, the Department should justify the need for the individual's name and address in the report and explain how these reports will be maintained.

Second, the Department should explain why a unique identifier would not accomplish the Department's objectives. Many supporters of name-based reporting also recognize that it may deter some persons from being tested. Hence, they also support anonymous testing to augment the name-based reporting. However, the use of unique identifiers could reduce the need for anonymous testing and reduce delays in treatment and prevention.

## **2. Reporting electronically. - Protection of the public health, safety and welfare; Economic impact; Reasonableness; Clarity.**

Sections 27.22(d)(1) and 27.32(c) and (d) require information to be reported electronically. How can the Department assure the confidentiality of information reported electronically?

Additionally, these sections and Section 27.32a(b) require electronic reporting in a manner specified by the Department. The Regulatory Analysis Form states that the Department will provide training and software.

Yet, the regulation does not specify how electronic reporting will be done or how security will be maintained. What equipment and software are reporters required to use? How much training is involved and how often is training offered? How much will this cost? Who will incur the cost, the Department or the reporters?

## **3. Coordination of amendments to Chapter 27. - Clarity.**

In the May 27, 2000 *Pennsylvania Bulletin*, the Department published proposed amendments to 28 Pa. Code Chapter 27 titled "Communicable and Noncommunicable Diseases" (Proposed Rulemaking #10-156). Included in that rulemaking are amendments to the same sections and lists of diseases being amended by this rulemaking, including Section 27.1 (definitions of *District office*, *LMRO* and *Local health department*), and Sections 27.2, 27.21, 27.22 and 27.32. How will the Department coordinate the amendments in these two rulemakings into a final-form regulation?

**4. Section 27.1. Definitions. - Clarity.**

*Local health department*

The last sentence for the definition of "Local Health Department" is substantive. For clarity, this should be moved to the body of the regulation.

*Perinatal exposure of a newborn to HIV*

Commentators questioned this definition because it indicates a need for a substantive judgment by a clinician. What is the intent of "subjecting to risk of HIV infection" and who is qualified to make this judgment? As this term is used in Section 27.32, a broad range of individuals may be required to report. Substantive questions involving risk should not be addressed in a definition. Reporters who are qualified to make this determination should be identified in the substantive provisions of the regulation.

**5. Section 27.2. Reportable diseases. - Clarity.**

This section, as well as Sections 27.32(a)(1) and 27.32(b), reference Acquired Immune Deficiency Syndrome (AIDS) "as defined by the CDC case definition." A citation to the definition used by the CDC should be included.

**6. Section 27.22. Reporting results indicative of certain infections or conditions by laboratories. - Reasonableness; Clarity.**

*Subsection (c)*

Subsection (c)(2)(ix) is duplicative of the diseases required to be reported in Subsection (b). Subsection (b) adds CD4 T-lymphocyte test results with certain counts to be reported. Subsection (c)(2)(viii) requires that the results of the test be reported. Therefore, subsection (c)(2)(ix) should be deleted.

*Subsection (d)*

Paragraphs (4) and (5) require test results to be reported within five days. Is five days sufficient time for the laboratories to report?

**7. Section 27.32. Reporting AIDS, HIV, CD4 T-lymphocyte counts, and perinatal exposure of newborns to HIV by physicians, hospitals, persons or entities, who diagnose AIDS or who receive or provide HIV and CD4 T-lymphocyte test results. - Fiscal impact; Reasonableness; Need; Implementation procedures; Clarity.**

*Subsection (a) – Entities and persons required to report*

This subsection requires a broad range of persons or entities to report AIDS diagnoses, HIV or CD4 T-lymphocyte test results to the state or local health department. There are five related concerns.

*Entities and persons who receive or provide test results*

First, the Department should carefully delineate the types of entities, facilities or persons who are required to report and are covered by Section 27.32d(a). The types of persons and entities covered by this section appear to be broad and vague. According to the Preamble, the intent is to

cover “case management organizations, drug and alcohol abuse treatment facilities, mobile vans and small clinics that do not have a physician present on a continuous basis.”

Yet, nothing in this section of the regulation indicates that it covers only these types of facilities. Section 27.32(a) identifies a reporter as: “A physician, hospital, or person or entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV or CD4 T-lymphocyte test results or provides HIV or CD4 T-lymphocyte test results....” [Emphasis added] Commentators raised several questions concerning the meaning and application of the phrase that appears above in bold type. It is also found in the title of Section 27.32 and in the text of Section 27.32d(a).

Various parts of this phrase such as “providing HIV services” could include a broad range of persons and entities. The same is true for the use of the words that would cover anyone “who receives” test results “or provides” test results to patients. For example, the phrase could include laboratory personnel. The Preamble states that this section “pertains to reporting by persons that are not laboratories,” and Section 27.22 in this regulation sets forth reporting requirements for laboratories. However, nothing in Section 27.32 explicitly states that it does not cover a laboratory.

#### *Licensed health care providers and facilities*

Second, Subsection 27.32(a) may be duplicative of other reporting requirements in existing regulations. This proposed regulation amends the list of reportable diseases in Section 27.2 by clarifying the definition of AIDS and adding the three other conditions listed again in this section: HIV, CD4 T-lymphocyte test results below certain levels and perinatal exposure of newborns to HIV. Requirements pertaining to reportable diseases for physicians, hospitals, school nurses and other health care practitioners are currently set forth in existing regulations at Sections 27.21, 27.23, 27.24 and 27.25. Listing these conditions as reportable diseases and then creating a new set of reporting requirements for them in Section 27.32 may create unnecessary confusion.

To prevent confusion, the Department should amend existing sections relating to mandated reporters, such as physicians and other licensed health care providers, to include the new reporting requirements for AIDS and the three related conditions. This is the same approach that the Department used for laboratories.

#### *Making a diagnosis of AIDS*

Third, Subsection 27.32(a) should be written to make it clear that only a physician may diagnose. As written, the subsection links a “hospital, or person or entity providing HIV services” to the words “makes a diagnosis.” Commentators expressed concern that the regulation should be clear that only licensed physicians can diagnose a disease.

#### *Responsible person*

Fourth, the regulation should identify the persons who will be responsible for making reports for entities that provide HIV services. This section does not indicate who, within an entity, is responsible for making the report. In contrast, Section 27.22(a) states that a person who is in charge of a laboratory must report.

*Fiscal impact of multiple reporters*

Fifth, the fiscal impact and purpose of this requirement are unclear. For example, a social worker, homeless shelter staff member, mental health center staff member and laboratory director may all file reports on the same individual. What is the need for numerous reports of a single case? What are the costs to the private sector when multiple reporters prepare and file reports? What will be the costs of effectively processing data from thousands of reporters, eliminating duplicates and using the data to monitor, control and prevent disease?

*Section 27.32(b) – Contents of report*

*Paragraphs (8) and (9)*

Paragraphs (8) and (9) duplicate the list of reportable diseases in Subsection (a). Paragraphs (8) and (9) are not needed and should be deleted.

*Paragraph (10)*

Paragraph (10) requires the “probable mode of transmission” of the HIV virus as information included in the report to the Department. The Department plans to obtain this information from a report form that it will provide to reporters. However, the report form does not use the words “probable mode of transmission.” To avoid confusion, the regulation should use words similar to the form.

*Paragraph (14)*

Paragraph (14) requires “other information the Department determines to be relevant.” What “other information” will the Department consider to be relevant? If there is none, this phrase should be deleted. Otherwise, to facilitate compliance and improve clarity, this phrase should be replaced with the specific information required.

**8. Section 27.32a. Confidential and anonymous testing. - Protection of the public safety and welfare; Need; Reasonableness; Implementation procedures; Clarity.**

*Subsection (a) – State-designated anonymous testing sites*

This provision states that anonymous testing for HIV may only be provided at “State-designated anonymous testing sites.” The House Committee and Senators Mowery, Murphy and Hughes expressed concern regarding the availability of anonymous testing sites. Part of this concern is that the regulation does not describe the term “State-designated anonymous testing sites.” The Department should address these concerns by explaining how it will insure both access to and availability of anonymous testing. For example, will the locations and hours of operation of these sites be publicized?

*Subsection (b) – Reporting anonymous testing results*

This subsection requires anonymous test results to be reported in accordance with Section 27.32 without a patient name. Section 27.32 also includes other identifying information such as the address of the individual’s residence, date of birth, sex and race. If this information is required, how is it anonymous? Did the Department intend to include certain categories of information in Section 27.32? Why is this information required in an anonymous test?

**9. Section 27.32c. Department authority to require complete reporting. - Clarity**

We have two concerns. First, this section is unclear because it is one long sentence. It would be clearer if it were broken into two shorter sentences.

Second, it appears there is a typographical error. This section should be designated as 27.32c, rather than 37.32c.

**10. Section 27.32d. Record audits. - Clarity.**

Subsection (b) states that the Department may require “special reports of persons or entities required to report under this chapter.” There are two concerns. First, what are “special reports”? Second, Subsection (b) is missing a word. For clarity, the word “to” should be inserted between the words “chapter” and “ensure.”