

Comments of the Independent Regulatory Review Commission



Department of Health Regulation #10-209 (IRRC #3235)

Complete Reporting of CD4 T-Lymphocyte, Viral Load and Genotyping Test Results Relating to HIV

July 24, 2019

We submit for your consideration the following comments on the proposed rulemaking published in the May 25, 2019 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. Section 27.32a. Reporting AIDS, HIV, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable viral load results and genotype test results, and perinatal exposure of newborns to HIV. – Implementation procedures; Fiscal impact; Need; and Clarity.

Proposed amendments to this section will require the reporting of test results through the Department's electronic disease surveillance system (system). We have three concerns. First, in the Preamble and Regulatory Analysis Form (RAF), this system is referred to as "PA-NEDSS." To improve the clarity of the regulation, we suggest that "electronic disease surveillance system" be defined, and if appropriate, include a reference to "PA-NEDSS."

Second, language preceding the reference to the system states that reporters "shall" report using the system. The word "shall" imposes a duty or obligation. Based on information provided in the Preamble and RAF, it is our understanding that results can be submitted by manual data entry or by mail to the Department. If those manners of reporting are allowable, we suggest that the final regulation be amended to reflect those options.

Third, a commentator expressed concern that data submitted into the system still requires manual data entry, and the additional reporting requirements will increase the time and cost necessary to remain in compliance with the regulation. The commentator encourages the Department to develop a process in which data entry could be automated. In addition, the commentator is concerned with the possible duplication of data being submitted by multiple reporters. In the Preamble to the final-form regulation, we ask the Department to explain how the regulated community is to use the system. We also encourage the Department to work with the regulated community to ensure they understand how the system will work and the reporting options that are available to them. Finally, we ask the Department to address the concern about duplication

of data entry by multiple reporters. If this duplication is occurring, what is the need for multiple reporters? Can it be eliminated without hampering the Department's efforts to stop the spread of HIV?

2. Section 27.32c. Partner services relating to HIV and AIDS. – Clarity.

Proposed amendments to this section will eliminate the following language: “Counseling, testing referral and partner notification services shall be performed in accordance with the Confidentiality of HIV-Related Information Act [(Act)] (35 P.S. §§ 7601—7612).” In the Preamble, the Department explains that the regulations do not require a reference to the Act in order for the requirements of the Act to be followed. We agree with the Department's analysis. However, the language provides an additional level of notice to the regulated community. It also provides greater clarity to those that must comply with the regulation and the statute. For these reasons, we ask the Department to keep the language in the final-form regulation.

3. Miscellaneous clarity.

Subsection 27.4 (b) includes an outdated reference to the forthcoming implementation of the system. Subsection 27.4 (e) includes references to multiple methods of reporting. Subsection 27.22 (d) includes a reference to “electronic mechanisms.” We suggest that these subsections be amended to reflect the current terminology being proposed and also the current status of electronic reporting.