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

July 27, 2000

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

Re: IRRC Regulation #10-156 (#2119)
Department of Health
Reporting of Communicable and Noncommunicable Diseases

Dear Secretary Zimmerman:

Enclosed are our Comments. They are also available on our website at 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, Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
James Rankin
Joel Hersh

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation No. 10-156

Reporting of Communicable and Noncommunicable Diseases

July 27, 2000

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 has 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 If the final-form regulation is not delivered by June 26, 2002, the regulation will be deemed withdrawn.

1. General - Statutory authority, Protection of the public health, Reasonableness and Clarity.

Authorized departures from the regulations.

Section 27.9 would allow the Department to authorize an exception to any regulation in Chapter 27. Section 27.151(a)(1) would allow the Department to specify additional diseases that would prohibit donation of blood. The exception or addition expires after 90 days unless the Advisory Health Board (Board) acts to affirm it. These sections do not state what happens after the Board affirms an exception or addition.

A provision of the regulation may only be amended by promulgation of a new regulation. The Department should add language to state that if the Board affirms the Department's action, the Department will amend the regulation. In the alternative, the Board should explain its statutory authority for amending the regulation without going through the rulemaking process.

Additionally, the Department should consider incorporating by reference the Morbidity and Mortality Weekly Report's "Case Definitions for Infectious Conditions Under Public Health Surveillance" for the list of communicable diseases contained in the proposed rulemaking. This would be a viable alternative to authorizing an exception to any regulation in this chapter, if the regulation becomes outdated. Guidelines for documents that can be incorporated by reference can be found at 45 Pa.C.S. § 727 and 1 Pa. Code § 3.41.

Scope of reporting.

As defined in Section 27.1, the individuals responsible for reporting are "health care practitioners." Section 27.23 assigns the same reporting responsibility as health care

practitioners to institutions, orphanages and child care groups. Section 27.21a(a) contains the list of specific diseases, infections and conditions that a health care practitioner must report.

The proposed regulation assigns the same reporting responsibility to a number of different persons, who have varying degrees of skill, to identify diseases, infections and conditions. While physicians have the necessary expertise to diagnose, commentators stated that other persons included under the definition of “health care practitioner” and Section 27.23 could only provide a layman’s identification. What does the Department expect in reports from laymen? Can the reports be based on symptoms and suspicions, rather than identification?

Suggested additions and deletions of diseases.

Commentators suggested additions and deletions of diseases to several sections, including Sections 27.22(b), 27.43a(b)(2) and Section 27.201. We recommend that the Department review the commentators’ concerns, and explain in the Comment and Response document why each of those specific diseases was not included or was deleted.

SUBCHAPTER A. GENERAL PROVISIONS.

2. Section 27.1. Definitions. - Consistency with statute, Reasonableness and Clarity.

General.

This section defines six terms that are also defined in 35 P.S. § 521.2. We object to the definitions of the following terms that differ from the definitions contained in the statute: “communicable disease,” “isolation,” “local health officer,” “quarantine” and “reportable disease.” If the Department does not use the statutory definitions in the final-form regulation, it should justify the changes.

Child.

This regulation defines “child” as “[A] person 15 years of age or younger.” As many different definitions for “child” exist in this Commonwealth, the Department should clarify how the use of this specific definition was determined. How is a person between the ages of 16 to 21 classified?

Isolation.

The definition of “isolation” requires the “separation for the communicable period of an infected person or animal from other persons or animals....” Commentators have asked whether the Department should clarify “separation” because the definition, as written, could be interpreted to require any patient or resident with any infection to be isolated.

We understand that many different factors are considered to determine whether a patient, resident or animal should be separated, and what degree of separation is required. There are a number of factors for separation, including the disease, patient, resident or animal’s behavior, and current situation at the facility. Likewise, separation could entail complete isolation or simply moving the patient to a single-patient room.

These factors and situations are substantive and should be in the body of the regulation, not in the definition of “isolation.” Therefore, to avoid confusion over implementation of “separation,” the Department should include the factors involved in making a decision to separate, and what form separation could take, in Section 27.61, relating to isolation.

Local health department.

This definition states “[T]he Department will maintain a list of local health departments and revise the list when new local health departments are established.” That information is substantive, and should not be included in the term’s definition. The Department should consider moving that portion of the definition to Section 27.4, relating to reporting cases.

Additionally, will the list of local health departments be revised if a local health department is relocated, or closed? If so, the Department should amend the final-form regulation to reflect that intent.

Undefined terms.

The terms “pupil,” “school,” “school employee,” “clinically related health care service” and “child care provider” are used in this proposed rulemaking. To eliminate any confusion, the Department should consider defining these terms in either Section 27.1, relating to definitions, or within the sections where they are used.

3. Section 27.4. Reporting cases. - Reasonableness and Clarity.

Subsection (a) outlines how and where cases should be reported. Will the Department provide a list of addresses and phone numbers if one of the locations mentioned in Subsections (a)(1) – (a)(7) changes? If so, how will the Department notify health care practitioners and clinical laboratories of a change in location?

4. Section 27.7. Cooperation between clinical laboratories and persons who order laboratory tests. - Reasonableness and Clarity.

Testing.

Section 27.7 requires clinical laboratories and “persons who request (and order) the testing...” to share information. We have two concerns with this section. First, the term “the person who requests the testing” is unclear. Is that person the practitioner, or the individual (who may be a nurse, physician’s assistant or a member of the support staff) who actually contacts the clinical laboratory? The Department should resolve this ambiguity in the final-form regulation.

Second, Paragraph (1) uses the term “person who requests the testing.” Paragraph (2) uses “[A] person who orders testing.” Is there a difference between a person who “requests” and a person who “orders” testing? If not, the Department should use a uniform term throughout this section.

5. Section 27.8. Criminal penalties for violating the act or this chapter. - Protection of public health and safety.

This section outlines penalties for persons who violate any provision of this chapter. However, the regulation does not address the immediate measures a healthcare facility should take if a patient under the facility's care leaves the facility and exposes the public to disease. The Department should explain what a healthcare facility should do in this situation.

SUBCHAPTER B. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS.

6. General. - Economic impact, Need and Clarity.

Hepatitis C.

Commentators, including Representative Dennis O'Brien, Majority Chairman of the House Health and Welfare Committee, stated there is a need for more comprehensive reporting of viral Hepatitis C cases, including chronic as well as acute. The lists of diseases in Sections 27.21a, 27.22 and 27.43a require reporting of viral Hepatitis C. These sections do not specify whether the disease must be chronic or acute for reporting purposes. In order to have the appropriate information reported, the Department should clarify the reporting of Hepatitis C cases.

Duplicative reporting requirements.

Subchapter B requires multiple reporting of a single incidence of disease. Commentators outlined the following examples:

- Section 27.21a(b)(1) provides that a health care facility is not required to report a case if it reported the case previously. A clinical laboratory is also required to report under Section 27.22, even if it is part of the health care facility. In this instance, the regulations require two reports on one diagnosis within the same facility.
- Section 27.22(a) requires clinical laboratories to report. The regulation appears to require duplicative reporting when one clinical laboratory refers a case to another laboratory.

The Department should clarify whether only one report is required in these situations, or explain why duplicative reporting is needed and how the benefits outweigh the costs.

Complexity of reporting process.

Commentators believe the reporting requirements in Subchapter B are burdensome in two ways. First, the reporter is required to determine the appropriate local agency for the patient's residence, or which local agency is able to intervene. Second, when reporting to the Department, the point of submittal varies by the disease being reported. Commentators suggest simplifying the reporting process to improve the appropriate filing of reports. Among the suggestions is reporting to a single point that distributes the reports to the appropriate agencies. The Department should review the process for submitting reports, and explain why the current system is necessary.

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

Section 27.22. Reporting of cases by clinical laboratories. - Clarity.

Sections 27.21a(a)(2) and 27.22(b) require reporting of several diseases “in children up to 5 years or 60 months of age.” Why are both phrases “5 years” and “60 months” needed? For clarity, the Department should use the phrase “under 5 years of age.”

Under Section 27.21(a)(2), Chickenpox will become reportable three years after the adoption of the final-form regulation. The Department explains in the Preamble that Chickenpox has not been reportable since 1984. The three year delay is to allow the Department to obtain data before requiring reporting of Chickenpox. We question why the Department is including Chickenpox in this rulemaking before the data is available. The Department should consider including Chickenpox in a future rulemaking.

8. Section 27.22. Reporting of cases by clinical laboratories. - Protection of the public health.

Subsection (c) lists the content of reports. Commentators suggest adding “the source of specimen, results and range of normal values for the specific test.” The Department should consider adding these items to the reports.

9. Section 27.32. Reporting AIDS. - Protection of the public health and Need.

Section 27.32 is being deleted. Therefore, AIDS reporting will no longer be required from hospitals, healthcare facilities and institutions. Representative O’Brien expressed concern that, under the language of the proposed regulation, AIDS would no longer be a reportable disease. Because Section 27.21 requires physicians to report cases of AIDS, Section 27.32 should be retained in the final-form regulation.

10. Section 27.34. Reporting cases of lead poisoning. - Duplication and Clarity.

Subsection (a).

A commentator stated clinical laboratories don’t always determine whether the patient is pregnant. As the regulation is written, pregnancy is a criteria for reporting cases of lead poisoning. The Department should explain how a clinical laboratory would know or determine whether the patient is pregnant.

Why is the Department using the phrase “those persons under 16 years of age,” instead of the defined term “child” which includes persons 15 years of age or younger?

Subsection (i).

Paragraph (5) is a broad requirement for “[O]ther information as requested by the Department.” The Department should limit the scope of this information to the information needed to complete the form, as explained in Subsection (i).

Subsection (j).

Subsection (j) ends with the phrase “or other disciplinary action.” What other disciplinary action is the Department authorized to take under the statute?

SUBCHAPTER C. QUARANTINE AND ISOLATION.

11. Section 27.60. Disease control measures. - Clarity.

The last sentence of this section states that under certain circumstances a local health authority shall consult with and receive approval from the Department prior to taking disease control measures. The regulation should state how to request the Department’s approval, and whether the Department’s approval is in writing.

12. Section 27.71. Exclusion of pupils and staff for specified diseases and infectious conditions. - Economic and fiscal impact, Need, Reasonableness and Clarity.

Children and staff attending schools and child care group settings.

Prior to Section 27.71, the regulation is subtitled “Communicable diseases in children and staff attending schools and child care group settings.” However, the title and text of Sections 27.71, 27.72, 27.73 and 27.74 use other terms such as “pupils.” For clarity, the Department should review these sections and use defined terms consistently, including the subtitle.

Staff person who has contact with pupils; verification for readmission.

Section 27.71 requires pupils and staff persons who have contact with pupils that are suspected of having one of the listed diseases to receive verification from a school nurse or physician that the criteria for readmission has been satisfied. We have three questions regarding this section.

First, the term “staff person who has contact with pupils” is unclear. Who is included in this term? The Department should define this term in either this section or in Section 27.1, relating to definitions.

Second, if the timeframe for readmission has been satisfied (as noted in Paragraphs (1) through (15)), is it necessary for pupils and staff persons who have contact with pupils to receive verification for readmission from a school nurse or physician?

Finally, the regulation is limited to “school nurse” or physician verification for readmission. Commentators stated that not all schools have a “school nurse” readily available. Why is verification limited to a school nurse or a physician? Would verification from other medical personnel, such as a registered nurse or physician’s assistant, meet this requirement? We have the same concern in Section 27.73, relating to readmission of excluded pupils and staff.

13. Section 27.72. Exclusion of pupils and staff showing symptoms. - Reasonableness and Clarity.

Staff person and staff person who has contact with pupils.

This section requires persons in charge of a school to immediately exclude pupils or staff persons who show a number of different symptoms that could denote the onset or infection of a communicable disease. In Subsection (a), why is the phrase “pupil or staff person” used instead of “pupil or a staff person who has contact with pupils”? For consistency with the rest of the rulemaking, the Department should choose one of the two phrases, define it and use it consistently.

Inclusion of Diarrhea.

Also in Subsection (a), commentators have suggested including “diarrhea” in the list of symptoms that require persons in charge of a school to exclude pupils or staff members. They argue that the addition of “diarrhea” in this subsection would be consistent with other provisions in the regulation, specifically: Sections 27.76(a)(3) relating to exclusion and readmission of children and staff in child care group settings; 27.154(6) relating to restrictions on caregivers in a child care group setting; and 27.155(6) relating to restrictions on health care practitioners. The Department should include “diarrhea” in Subsection (a)(1) – (7), or explain this inconsistency.

Subsection (b).

Subsection (b) states: “[T]he Department will periodically determine and publish... what increase in absenteeism constitutes an unusual rate of absenteeism.” The term “periodically” is unclear. Will the Department publish such information quarterly, annually or monthly? Will the information be published in the *Pennsylvania Bulletin*? The Department should establish a timeframe for “periodically,” and state where the publication will occur.

This subsection also requires schools to maintain records of exclusions and review these records to determine when unreasonable rates of absenteeism occur. Is the school then required to forward that information to the Department? If so, what forms and procedures are required to report this information? The final-form regulation should clearly state that schools need to submit this information, and should specify the reporting process.

14. Section 27.76. Exclusion and readmission of children and staff in child care group settings. - Reasonableness and Clarity.

Invasive H. influenza disease.

Commentators have noted that the Department should delete Subsection (a)(8), which deals specifically with “invasive H. influenza disease.” As noted in **Issue #1**, we understand that the Department utilizes the Morbidity and Mortality Weekly Report’s “Case Definitions for Infectious Conditions Under Public Health Surveillance” (Report), for determining which communicable diseases need to be reported. As “invasive H. influenza disease” is not included in the Report, we question its inclusion here. The Department should explain.

Screening.

Subsection (b)(3) requires caregivers at child care group settings: to screen “each child by staff at the time the child is brought to the child care group setting for the presence of a condition which requires exclusion.” We have three concerns with this subsection.

First, does this requirement mandate that caregivers at a child care group examine every child every day for the presence of an exclusionary disease, or only if the child is suspected of having an exclusionary disease? The Department should clarify its intention in the final-form regulation.

Second, the regulation states that caregivers should screen each child for “the presence of a condition which requires exclusion.” Does this mean that the caregiver is responsible for making an accurate diagnosis of a child’s condition, or that the caregiver should screen for *symptoms* of exclusionary diseases? The Department should explain.

Finally, how will the caregiver report the presence of an exclusionary disease to the Department? Will there be a form approved by the Department? Is there a process the caregiver must follow? The Department should fully explain the process for caregivers to report exclusionary diseases in the final-form regulation.

15. Section 27.77. Immunization requirements for children in child care group settings. - Clarity.

Certificates of immunization.

Subsection (a)(4) requires certificates of immunization to be completed and signed for each child enrolled in a child care group setting. This subsection also requires that these certificates be “periodically updated by the caregiver.” The term “periodically” is unclear. The Department should include a timeframe.

SUBCHAPTER D. SEXUALLY TRANSMITTED DISEASES, TUBERCULOSIS AND OTHER COMMUNICABLE DISEASES.

16. Section 27.87. Refusal to submit to treatment for communicable diseases. - Clarity.

The second sentence of Subsection (b) is long and complex. The Department should amend this sentence to make it clearer.

17. Section 27.89. Examinations for syphilis. - Consistency with the statute, Protection of the public health and Clarity.

Subsections (a)(1) and (c) state that the Department will publish the rate of syphilis in the *Pennsylvania Bulletin* “as necessary.” What is the purpose of publishing the rate of syphilis, why is publication necessary and what criteria will be used to determine when it is necessary?

**SUBCHAPTER E. SELECTED PROCEDURES FOR PREVENTING DISEASE
TRANSMISSION**

18. Section 27.151. Restrictions on the donation of blood, blood products, tissue, sperm and ova. – Consistency with statute and Clarity.

Subsection (a) states that, “a person who is known to be infected with a causative agent of a reportable disease is not allowed to donate.” The Department should add “or suspected” in accordance with 35 P.S. § 521.4(a).

19. Section 27.152. Investigation of cases and outbreaks. - Clarity.

In Subsection (b), a representative may be required to present “documentation to establish that he is an authorized representative of the Department or local health authority.” What kind of documentation is required? Would a nametag meet this requirement?

20. Section 27.158. Special requirements for shigellosis. - Protection of the public health and Clarity.

This section begins with the phrase “[A] household contact of a case of shigellosis.” This phrase is unclear. The Department should either provide examples or define the term “household contact” in this section of the final-form regulation.

21. Section 27.161. Special requirements for tuberculosis. - Clarity.

In Subsection (b) the term “substantial” is used to describe a timeframe. The Department should provide a specific timeframe and delete the term “substantial.”

SUBCHAPTER F. MISCELLANEOUS PROVISIONS.

22. Section 27.201. Disposition of articles exposed to contamination. - Protection of the public health and Clarity.

This section provides an exception for when the transmission of articles is made “with proper precaution.” The regulation should explain or reference what “proper precaution” must be taken.

23. Section 27.202. Lease of premises occupied by a person with communicable disease. - Clarity.

The phrase “[cleaned] to the satisfaction of health authorities” is being deleted. What standard must be met?

24. Other clarity issues.

Portions of the regulation use vague phrases or have typographical errors. The Department should review the following:

- Section 27.4(c) requires that “[A] case shall be reported using the appropriate case format.” The Department should explain what the “appropriate case format” is, and how reporters will be made aware of the proper format for reporting.
- Section 27.23 begins with the phrase “[E]xcept as otherwise set forth in this section.” Why is this phrase needed?
- If the Department retains “invasive H. influenza disease,” “influenza” should be replaced with “influenzae” in Section 27.76.
- Subsections 27.84(a) and (b) reference an “appropriate” remedy. Subsection 27.87(b) references an “appropriate” institution. The Department should clarify what is considered “appropriate.”
- Section 27.203 requires “appropriate precautions” to prevent the spread of disease. This phrase is vague. The Department should give examples of what it considers to be “appropriate precautions” in the final-form regulation.