# RULES AND REGULATIONS

## Title 28—HEALTH AND SAFETY

### DEPARTMENT OF HEALTH

### [28 PA. CODE CHS. 27 AND 211]

### Reporting of Communicable and Noncommunicable Diseases

The Department of Health (Department) and the State Advisory Health Board (Board) adopt amendments to Chapters 27 and 211 (relating to communicable and noncommunicable diseases; and program standards for long-term care nursing facilities) to read as set forth in Annex A.

A. *Purpose and Background*

The Department's regulations relating to communicable and noncommunicable diseases in Chapter 27 were first promulgated in 1959. Since that time, there have been dramatic changes in society, technology and the environment that make revision of these regulations a necessity. Where once outbreaks of disease could be held within geographical boundaries, today, the speed of air travel and the global economy are fostering the worldwide spread of life-threatening pathogens. Persons infected in one place can be on the other side of the world by the time symptoms appear. New infectious agents are emerging which require new prevention and control techniques. New conditions are becoming recognized which benefit from early detection and treatment. Disease outbreaks continue to occur, antibiotic resistance of some diseases is spreading and previously controlled agents are in resurgence. Although more exotic diseases like Group A streptococcus (flesh eating bacteria), the hantavirus and the ebola virus receive most of the attention from the media, other infectious diseases continue to pose public health problems. For example, within the past several years there have been outbreaks of cryptosporidiosis, E. coli 0157:H7, Salmonella enteritidis, hepatitis A and shigellosis. There are strains of multidrug resistant tuberculosis, which reduces the ability to treat the disease, and in recent years there have been reports from Japan of evidence of resistance of Staphylococcus aureus to the drug, Vancomycin, long considered the last line of defense.

This Commonwealth is not immune from these public health threats. A few examples of threats to the public health within this Commonwealth over the past few years include a 1996-1997 outbreak of cyclospora caused by Guatemalan raspberries, ongoing Salmonella enteritidis outbreaks caused by, among other things, infected eggs; rabies outbreaks from 1991 to the present; a shigellosis outbreak in 1996 that spread from Ohio to Pennsylvania; multidrug resistance to tuberculosis; and the ongoing epidemic of Lyme disease. More recently, concerns relating to the possibility of bioterrorism and the Commonwealth's response have arisen. The Department has chosen to revise the regulations to ensure that the disease control and prevention needs of changing diseases and conditions, and current health care priorities are adequately addressed.

The Department, with the approval of the Board, published a proposed rulemaking at 30 Pa.B. 2715 (May 27, 2000), and provided a 30-day public comment period. One commentator raised an issue regarding the telephone number for contacting the Department listed in the proposed rulemaking. The number did not work, and the commentator requested that the public comment period be extended for 1 week. The Department chose not to extend the comment period since the commentator did manage to contact the Department by telephone and provide written comments, and an accurate address for the submission of comments was included in the regulations.

The Department received many comments to the substance of the proposed rulemaking as well. The comments and the Department's responses to them appear in the summary of this final rulemaking.

If a section is not mentioned in the summary, no comments were received on that section, and it was adopted as proposed.

B. *Summary*

*CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES*

*Subchapter A. GENERAL PROVISIONS*

*General Comments*

Several of the general comments that the Department received involved the manner in which the Department requires reporting to be done.

*Comment*

These reporting requirements would require a separate system that would duplicate, and be less comprehensive and less current as a health promotion tool than the existing reporting system in place for child care centers and group homes regulated by the Department of Public Welfare (DPW), using a child health assessment form, no. CY51. This form uses a Nationally recommended routine preventive health services schedule, including vision, hearing, anemia, growth and lead, health history and physical examination findings as well as documentation of vaccinations. This form should not be duplicated or supplanted by any form or reporting requirements developed by the Department. In doing so, would lessen the effectiveness of the more comprehensive system in place in DPW licensed facilities.

*Response*

The Department has not changed the proposed rulemaking in response to this comment. The Department is the State agency responsible for disease control and prevention throughout this Commonwealth, and has the authority to require reporting of those diseases, infections and conditions that it, with the review and approval of the Board, determines should be reported to the Department to carry out this responsibility. See generally, the Disease Prevention and Control Law of 1955 (act) (35 P. S. §§ 521.1—521.21). DPW, as the licensing agency for certain facilities, has certain statutory responsibilities, which differ from those of the Department. The information the two agencies gather is different. The Department does not require reporting of vision, hearing, anemia and growth data through its communicable and noncommunicable disease regulations, nor of complete health histories or physical examinations, since the Department is not responsible as part of its disease prevention and control function for the healthy growth and development of each individual within a licensed facility. The Department is

responsible for the health and welfare of all the citizens of this Commonwealth. The list of reportable diseases, infections and conditions that the Department determines should be reported, the information included in those reports, and the manner in which the reporting is to be done, are driven by this broader role.

*Comment*

The reporting requirements are burdensome, since a reporter is first required to determine the appropriate local agency for a patient's residence, or which agency is able to intervene. Then when reporting is made to the Department, the point of submittal differs by the disease being reported. The Department should review the process and explain why this system is necessary.

*Response*

The Department made some changes to the regulations based on these comments.

The Department will not require, at this point, that all reports be made electronically, and to one location within the Department, given the cost and technological issues involved. The Department has added language to the regulations stating its intent to phase in electronic reporting for all reporters as it implements components of the National Electronic Disease Surveillance System (NEDSS). See § 27.4(b) (relating to reporting cases). At the time this occurs, reports will be made to one location within the Department, or to the appropriate local morbidity reporting office (LMRO).

The Department intends to begin piloting its modifications to NEDSS in several of its health districts in the fall of 2001. As the Department becomes ready to implement its electronic system for the reporting of various diseases, the Department will notify in writing all reporters who are licensed in this Commonwealth (for example, hospitals, physicians, nurses, day care centers, drug and alcohol abuse treatment facilities), and will also publish notice of this requirement in the *Pennsylvania Bulletin*. Notice will be given at least 6 months in advance of the date on which electronic reporting is to occur.

The Department is providing reporters with the electronic application to be used to make reporting electronically easier and less costly. Further, reporters who may not have access to the Internet may still make initial reports of cases by telephone. When this occurs, the Department explains to the reporter how the complete report should be made. This will continue to occur. See § 27.4(c).

Paper reports of the listed diseases, infections and conditions will continue to be made by reporters, including laboratories, to one of the LMROs, which will consist of the Department's six district offices and the ten county and municipal health departments (local health departments), until the Department notifies reporters that reports must be made electronically.

The Department is currently encouraging electronic reporting by laboratories, because having laboratories report electronically is quicker than paper reporting and makes it easier for the Bureau of Epidemiology (Bureau) to review and disseminate important information to the various Departmental public health programs (the Department's TB program for example), the district offices, and the local health departments that utilize that information for case management and other services. The Department is aware that large National and regional laboratories performing testing for many states find it burdensome to sort Commonwealth reports for transmission to different locations within this Commonwealth. If electronic reporting is done by laboratories, however, the Department is requiring that those electronic reports be made to a single location in the Department.

The Department requires laboratories to report directly to it rather than to the LMROs because many of the laboratory's reports could be reports of repeat testing. Patients may also visit more than one provider and be tested multiple times. The laboratory has no way of knowing whether a test is the initial test a provider orders on a patient or a repeat test, or a repeat test ordered by a second provider. The Department, in the Bureau, is able, with software it possesses, to electronically match information in those reports with information from reports it already received and placed in its Statewide reporting databases. The Department can then identify multiple reports on the same individual and consolidate unduplicated useful information in one case record. Local health departments and the Department's district offices do not have this capability at the present time.

The Department is requiring all reports other than electronic laboratory reports to be made to LMROs for several reasons. For local health departments and the Department to provide follow-up services and information, the local health department or district office should have a relationship with the practitioner-reporter. This required contact by the reporter will enable the reporter to begin that relationship. From the standpoint of efficiency, the requirement will provide the information to enable and expedite case tracking and other services directly to the local health departments and Department staff that do the actual case investigation, follow-up, counseling, referral and partner notification.

Further, to require that all paper reports go to one office within the Department would be burdensome for that office, and would take too long to sort and redirect. Certain reports are time sensitive, for example, reports of diseases of the newborn. A child with maple syrup urine disease (MSUD) must be identified and treatment begun within 7 days of birth or serious impairment to or death of the child will occur. For this reason, the regulation requires those reports to be sent directly to the specific office within the Department with responsibility for managing that disease, infection or condition.

With respect to issues involving the requirement of multiple reporters, the Department requires reporting from all different types of reporters, including practitioners, facilities, laboratories, other providers and the public for several reasons. The Department does not want possible reporters to self-censor, based on their assumption that another person will make the report. That could lead to under-reporting, and jeopardize the ability of the public health system to positively impact the health of infected individuals and their contacts. If the Department and local health departments are unaware of cases, they will be unable to offer or provide follow-up, including counseling and referral information, and perform case investigation.

The Department also receives different information from different reporters. For example, a report by a laboratory is a confirmatory report of a disease or condition diagnosed by a health care practitioner. From heads of institutions the Department will receive information that is neither a diagnosis nor a confirmed report, but a suspicion that may help to identify a disease outbreak. The monitoring of the disease in the patient is dependent on receiving information from a practitioner as well as a

laboratory, as is the monitoring of the disease in the population as a whole. Information relating to opportunistic infections, referrals, mode of transmission and treatment are not shared by a practitioner with the laboratory, and, therefore, the Department would not be able to obtain this type of specific information from laboratories if laboratories alone were to report. A provider would not release this type of information to a laboratory because of its confidential nature. A laboratory does not need to be aware of the mode of transmission of a disease or types of referrals made for the individual to perform its licensed function—conducting laboratory tests of specimens.

The more specific the information received by the Department from all reporters, the more likely it is that the Department will be able to match information obtained from other sources, sometimes incomplete, and obtain complete information on each reported case. The more complete the demographic picture of the individual whose results are being reported, the easier it is for the Department to track the disease in this Commonwealth for purposes of implementing prevention measures, including targeting funding to affected populations. Further, the more complete the information on a specific individual the Department obtains, the easier it becomes for the Department and local health departments to provide follow-up services to that individual. For example, with a case of infectious tuberculosis, the Department will provide treatment, including directly observed therapy, to ensure that the case is cured, and will also locate and test and treat contacts as necessary. In the case of sexually transmitted diseases, the Department and local departments locate and offer counseling and testing services to partners of individuals who test positive.

*Section 27.1. Definitions.*

This section explains the terms used in Chapter 27.

The Department has revised the proposed definition of "LMRO—local morbidity reporting office" to match the language proposed for this term at 31 Pa.B. 2126 (April 21, 2001). The Department believes that the offices receiving reports should be limited to those local health authorities with the greatest experience in this area. These include only the Department's six district offices and the ten local health departments.

*Comment*

There are many different definitions of the term "child" used in this Commonwealth. The Department should explain why it has defined "child" as a person 15 years of age or younger.

*Response*

The Department took its definition of "child" from the definition of "child" used by DPW in its definition relating to day care (see 55 Pa. Code Chapters 3270—3290). The Department has since been informed by the DPW that DPW's definition of "child" may change during the revision of DPW's regulations on these topics. The Department has, therefore, reviewed its definition, and has determined that it would be more appropriate in the context of these regulations to define a child as a person under 18 years of age. When the regulatory context requires a different age limit, for example, in the area of newborn screening, the language of the regulation will reflect that fact.

*Comment*

The definition of "child care group setting" properly encompasses all types of group care in this Commonwealth, since group care among young children increases their exposure to and risk of contracting a communicable disease. By defining this term broadly, the Department has appropriately addressed that risk. However, the definition should be adjusted to account for the practical limitations of checking vaccination status in settings where group care is transient and infrequent, for example, in day care provided during church services, court proceedings, in shopping malls and other temporary settings. The Department should modify the regulations to apply where four or more children unrelated to the operator receive care for 10 or more hours in any week, or for 40 or more hours in any month.

*Response*

The Department has not changed the definition. It was not the Department's intention to capture all the types of care settings discussed by the commentator through its regulations relating to immunization in child care group settings. The Department has included in § 27.77 (relating to immunization requirements for children in child care group settings) a provision which states that a caregiver who does not serve as a caregiver for at least 40 hours in at least 1 month is not covered by the regulation. See § 27.77(d)(iii).

*Comment*

The definition of "communicable disease" is broad. Does this mean that if a disease is not listed in the regulations, it will not be regulated? Can a facility determine its own procedures for control of a nonlisted disease?

*Response*

The definition of "communicable disease" is intended to be broad; the definition is taken from the act, which defines the term broadly. The Department has revised the definition to clarify it, and to make it clear that it is not the act of transmission that makes the disease communicable, but that fact that it is capable of being transmitted to a susceptible host.

If the disease is not listed in the regulations as a reportable disease (defined by the act as any communicable disease made reportable by regulation), it still comes under the act and regulation if there is an outbreak of that disease. A nonlisted disease becomes reportable if an outbreak of that disease occurs. "Outbreak" is defined as "any unusual increase in the number of cases of a disease, infection or condition, whether reportable or not as a single case, above the number of cases that a person required to report would expect to see in a particular geographic area or among a subset of persons (defined by a specific demographic or other features)." See § 27.1 (relating to definitions).

With respect to the question concerning control procedures for a nonlisted disease, if there is not an outbreak of the nonlisted disease, the Department will most likely not be involved in the matter (unless requested to do so by the facility). If an outbreak is reported, the Department will be involved in the investigation, and will provide recommendations regarding disease control and prevention.

*Comment*

The definition of "health care facility" is not clear. It contains a provision excluding an office used primarily for the private practice of a health care provider where no clinically related health care service is offered. The Department should add a definition of "clinically related health care service" to clarify the definition.

*Response*

The Department's intention was to use the definition of "health care facility" from the Health Care Facilities Act (35 P. S. §§ 448.101—448.904b). It has revised the definition to reflect the definition applicable to Chapter 8 of that statute (35 P. S. §§ 448.801—448.821) (relating to licensure of health care facilities). The phrase, "clinically related health care services," was in the definition of "health care facility" used in the certificate of need provisions in Chapter 7 of that statute (35 P. S. §§ 448.701—448.712), which sunset in December of 1996. The Department has deleted that phrase from the definition in this section, and has revised the definition to reflect the language in Chapter 8 of the Health Care Facilities Act. The Department has expanded that definition to include drug and alcohol abuse treatment facilities as health care facilities for the purposes of these regulations. The client population in drug and alcohol abuse treatment facilities is particularly susceptible to certain communicable diseases, for example, tuberculosis. The need to control the spread of disease in this population is acute.

*Comment*

The definition of "local health authority" does not include a sanitary board. Unless sanitary boards fall under some other definition, they should be included here.

*Response*

The Department agrees, and has added language to the definition of "local health authority" to include sanitary boards.

*Comment*

The Department should add language to the definition of "local health department" stating that the Department will revise the list when a local health department is closed, as well as when one is established. This language should then be moved to § 27.4 (relating to reporting cases), since the provision is a substantive one.

*Response*

The Department agrees that its list of local health departments should be revised when local health departments are closed, as well as when they are established. The Department is removing the language from the regulation altogether, however, as the Department's intention to maintain this list need not be included in the regulations. The Department will maintain a list of local health departments and will update the list when any change occurs.

*Comment*

The definitions of "modified quarantine," "segregation" and "surveillance of contacts" appear in two places in the regulations. They are repeated at 30 Pa.B. 2730 and 2731.

*Response*

The definitions of these terms were not repeated. They were bracketed at 30 Pa.B. 2730 to identify language that the Department was proposing to remove from the definition of "quarantine," which had included definitions for all three terms. The Department has revised the definition of "quarantine" to remove definitions for "segregation," "modified quarantine" and "surveillance." The Department has separately defined "segregation" and "modified quarantine," and has added a definition for "surveillance of disease." These changes are made because of the importance of each term in performing disease control.

*Comment*

The term "surveillance" has two different meanings. One meaning appears in the context of surveillance of disease, the other in the context of surveillance of contacts. The Department should change the term "surveillance of contacts" to "monitoring of contacts" to take these differences into account.

*Response*

The Department agrees and has amended this section accordingly.

*Comments*

The definition of "health care practitioner" as written will include first responders, emergency medical technicians, prehospital registered nurses and paramedics. The training provided to these individuals will not necessarily prepare them to diagnose the diseases listed in the regulations. There will need to be a revision to training requirements to allow them to do this. Since patients are taken to hospitals, staff in emergency rooms will handle this reporting more appropriately. The Department should exempt persons identified in the Emergency Medical Services Act (35 P. S. §§ 6921—6938) from being required to report, or should provide immunity from the reporting requirements.

What does the Department expect in reports from laypersons? Can reports be based on symptoms and suspicions, rather than identification?

*Response*

Neither the act nor the regulations condition reporting solely based on diagnosis of disease. It is not the Department's intention to require layperson, or health care practitioners who are not trained or permitted by the scope of their practice, to make diagnoses. The act requires that knowledge or suspicion of a disease be reported. See 35 P. S. § 521.4 (relating to reports). If a first responder, emergency medical technician, prehospital registered nurse or paramedic has reason to believe, through symptoms or for other reasons, that an individual has a reportable disease or condition, those individuals are required to report. A report from a layperson could include that person's observations of the physical state of the individual, or could be a relating of the person's concerns that the individual is exhibiting something unusual that should be reported to the Department. The Department will then ask the layperson questions designed to elicit information which will allow the Department to make a determination of what further action is necessary, if any.

As previously discussed, the Department intentionally drafted these regulations to require reporting from as many types of individuals as possible, even when reporting could be duplicative.

*Comment*

Does a certified nurse's aide (CNA) have to report communicable diseases?

*Response*

A CNA is required to report the listed diseases, infections and conditions to the same extent that any member of the public is required to report.

*Comment*

The Department should define the terms "pupil," "school," "school employee" and "child care provider."

*Response*

The Department has replaced the term "pupil" with the term "child" or "children" throughout Chapter 27. Child is defined in the regulations. The Department has been unable to locate the terms "school employee" or "child care provider" in the regulations. The Department has not defined the term "school" since this is a term used throughout the Public School Code of 1949 (24 P. S. §§ 1-101—26-2606-B), and the regulations promulgated under that statute by both the Department (see Chapter 23 (relating to school health)) and the Department of Education (see 22 Pa. Code (relating to education)).

*Comment*

The Department should simplify the definition of "outbreak." An outbreak should be defined as the excess of the expected incidence of disease within a particular geographic area or population in a specified time period. This definition comes from the *Epidemiological Handbook* published by the Association of Professionals in Infection Control and Epidemiology (APIC).

*Response*

The Department disagrees with this comment. The definition of "outbreak" used by the Department in its regulations is the definition of the American Public Health Association (APHA) and is a more universally accepted definition for this term. The Department has not changed the definition.

*Comment*

The definitions of "communicable disease," "isolation," "local health officer," "quarantine" and "reportable disease" differ from the definitions of these terms included in the act. The Department must explain why these definitions have been changed.

*Response*

The Department has not changed its regulation in response to this comment. Since the statute was enacted in 1955, the meanings of these terms have been refined by public health practice. The Department has updated the language used in the statute, to clarify the meaning of these terms, but has not substantively changed them.

*Comments*

The definition of the term "isolation" should be clarified since it appears that the language could be interpreted to require isolation of any patient or resident with a communicable disease.

The Department should include the factors and situations used in determining whether the patient, resident or animal should be separated, and what degree of separation is required. This should be done in § 27.61 (relating to isolation) and not in the definition of the term "isolation" in this section.

*Response*

The Department has not changed the proposed definition of "isolation." The purpose of § 27.61 is to enable the Department or a local health authority to isolate a patient or resident with a communicable disease, depending upon the circumstances of the case. Whether isolation will occur, and what form it will take depends on the nature of the diagnosed disease, the characteristics of the individual (including how the individual is complying with disease control requirements), and the type of facilities available. However, a general determination of what control measures are necessary, not just decisions of how isolation would be effected, is based upon these considerations. Therefore, the Department has changed the language of § 27.60 (relating to disease control measures) to include the relevant considerations, rather than § 27.61, which relates specifically to isolation.

*Section 27.3. Reporting outbreaks and unusual diseases, infections and conditions.*

This section requires the reporting of outbreaks of disease, and the incidence of any unusual disease, infection or condition by any person who suspects a public health emergency.

*Comment*

Is reporting of an unusual disease, infection or condition required when it is suspected or when there is a microbiological or other test, such as sputum smear, confirming the presence of the disease or infection? The Department should provide specific instructions with respect to reporting these matters.

*Response*

The Department has not changed the proposed rulemaking. This section specifically requires reporting of an unusual disease, infection or condition whenever a person suspects a public health emergency. The existence of a confirmatory laboratory report or other test is not required. This section is intended to reach anyone who may suspect that a public health emergency is occurring, regardless of whether that person has access to confirmatory test results. The instructions on how to report are included in § 27.4.

*Section 27.4. Reporting cases.*

This section explains generally how and where reporting of diseases is to occur.

*Comment*

Will the Department provide health care facilities and health care practitioners with a list of address or phone number changes if there is a move of the locations to which diseases and conditions are to be reported? Will the Department notify individuals of the changes?

*Response*

The Department will provide a list of addresses and telephone numbers for the LMROs and the specific Department offices to which certain specified diseases are to be reported. The Department will publish this list in the *Pennsylvania Bulletin*, and update it when it becomes necessary. The Department will also provide the list upon request.

Subsection (d), proposed as subsection (b), does contain the official names of the offices in the Department to which reports may be made. Individual regulations relating to specific diseases, infections or conditions specify to which of these offices the report is to be made. Although the names of the specific offices may change, the Department address, P. O. Box 90, Harrisburg, PA, will not.

*Comment*

Subsection (a) requires health care facilities and health care providers to report cases to the local health authority where the individual resides. It is easier to report to the local health authority where the practitioner or facility is, rather than to determine to which local health authority to report. The local health authority then determines where to report. This is currently being done.

*Response*

The Department agrees, and has changed the regulation as recommended.

For clarification, subsection (a) refers to LMROs, and not local health authorities. An LMRO includes county/municipal health departments and the Department's six district offices, excluding all other local health authorities.

*Comment*

Clinical laboratories reporting electronically should be sending all reports, except cancer reports, to a central location. Proposed subsection (b)(2)—(7) which requires reporting to specified offices within the Department, should be deleted.

*Response*

The Department has made some changes to the proposed rulemaking in response to this comment. The changes go beyond what type of reporting is required by laboratories, since this section addresses reporting of all reporters. Cases of cancer, AIDS, PKU, MSUD, hypothyroidism, sickle cell hemoglobinopathies and lead poisoning will still be reported to the particular office designated in the sections relating to reporting those matters. See, for example, § 27.33 (reporting cases of cancer). If and when the Department becomes ready to integrate reporting of these diseases, infections and conditions into its electronic disease surveillance system, the Department will publish notice of that fact 6 months before the change in reporting is to occur. Until that time, reports of these diseases infections and conditions will continue to be made to specific offices within the Department. The remainder of the reportable diseases, infections and conditions listed in Subchapter B (relating to reporting of diseases, infectious and conditions) will, however, either be reported to the LMRO where the case is diagnosed or identified, in the case of paper reports; or to the Division of Infectious Disease Epidemiology, in the case of electronic reporting by laboratories. The Department has therefore deleted proposed subsection (b)(3)—(5) in what is now subsection (d).

*Comment*

Proposed subsection (c) requires reporting to be done using the appropriate case format. The Department should explain what the case format is.

*Response*

Proposed subsection (c) is adopted as subsection (e). The Department, as part of a National effort, is developing a web-based disease reporting system with a generic report format that will capture disease specific information. However, providers will still be able to make initial reports by telephone if their financial considerations or lack of state-of-the-art reporting equipment so dictates. The Department provides paper case report cards to reporters. These cards, when returned to the Department, provide basic information regarding the case, and enable the Department to begin its case investigation.

*Section 27.5a. Confidentiality of case reports.*

This section states the general rule that all information gathered by the Department and local health departments under the act is confidential and will not be released, and also states the limited exceptions to that rule.

The Department received no comments on this section, but has added language to clarify that only those employees of the Department and local health departments who have a legitimate reason to view the information may do so.

*Section 27.6. Disciplinary consequences for violating reporting responsibilities.*

This section states that a licensed facility or practitioner who fails to comply with the regulations may be referred to the appropriate licensure board for disciplinary action.

*Comments*

The Department has no legislative authority to threaten that disciplinary action might be taken against a practitioner's license as a result of the practitioner's failure to report in any particular instance. The provision should be deleted.

The Department should modify its regulations to state that only a willful violation of the regulations or a demonstrated pattern of noncompliance will be reported to the appropriate disciplinary board, since the reporting requirements are complex.

*Response*

The Department has not changed the proposed rulemaking in response to these comments. The Department does not need specific legislative authority to refer a failure to comply with the law of the Commonwealth to a disciplinary board or licensing agency. The decision to take action is up to the disciplinary board or licensing agency. Further, these reporting requirements, with very little change, have been in place since 1955. The Department has written the regulation to apprise practitioners that the Department has the discretion to refer a practitioner's failure to satisfy reporting responsibilities to the appropriate licensure or disciplinary board. The Department's decision to do so would be based on all the circumstances involved in the case, including the nature of the violation, and whether it is part of a demonstrated pattern of noncompliance.

*Comment*

The language in the regulation that refers to disciplinary consequences against a physician who fails to report is troublesome. There is not sufficient detail in the regulations to understand under what circumstances disciplinary consequences would occur, whether there is an appeal process and what actions would be taken against physicians. If the Department wishes to increase reporting, it should establish a simple process for doing so that is available 24 hours-a-day, 7 days-a-week.

*Response*

As already stated, the regulations state that a physician's failure to report may be referred to the appropriate licensing board. That board, if it found sufficient reason to take action, would provide the necessary due process requirements. The Department itself cannot take disciplinary action against a physician. The Department does, however, have the authority under the act to institute a prosecution to fine someone who fails to comply with the act.

With respect to the comment regarding a continuous reporting system, the Department currently maintains on-call staff to respond as quickly as possible, 24 hours-a-day, 7 days-a-week, to reports of those diseases and infections that require immediate intervention. The Department's electronic reporting system will allow for 24-hour reporting of all diseases, infections and conditions even though the regulations do not require 24 hour reporting for all diseases, infections and conditions.

*Comment*

There should be a more aggressive educational approach toward improved physician reporting of diseases.

Disciplinary action should not be taken against practitioners for failure to report. Subsection (c) should be deleted.

*Response*

The Department has not changed the proposed regulation in response to this comment. While the Department agrees that education is necessary, and is pleased with the commentator's willingness to aid in this undertaking, the Department believes it is important to underscore the necessity of prompt and complete reporting for every reportable disease and condition. Subsection (c) states that the Department may refer a practitioner's failure to report to the appropriate disciplinary board for action; it is not the Department's intention to do so unless the action is repeated and flagrant. It is up to the licensing boards, of course, to investigate and determine whether disciplinary action is necessary under the terms of the relevant statutes, for example, the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45) and the regulations promulgated thereunder.

*Comment*

This section does not contain disciplinary consequences for child care group settings.

*Response*

The Department agrees that language relating to child care group settings parallel to that for other licensed facilities and practitioners should be included in the regulation. The Department has added that language stating that the Department may refer the child care group setting to the appropriate licensing agency for appropriate action. The decision to take action would then be up to that licensing agency.

*Comment*

Will there be an expected order of reporting, so that one person reports first, another reports second, and so on? If one report is filed, does every other person connected with that case have to file a report? Who is required to file what reports?

*Response*

Who is required to report what is clearly set out in the Department's regulations. The reporting responsibilities in the Department's regulations are categorized by the type of person or entity that is required to report them. For example, § 27.22 (relating to reporting of cases by clinical laboratories) lists the diseases, infections and conditions clinical laboratories are required to report. Section 27.21a (relating to reporting of cases by health care practitioners and health care facilities) lists the diseases, infections and conditions health care practitioners and facilities are required to report.

The Department has already addressed why multiple reports of the same case are required when multiple persons have knowledge of the case.

*Comment*

Do reporting practitioners have to communicate to other involved health care practitioners that a report has been made? Do reporting practitioners have to report the findings in a timely manner to other health care practitioners that need to know the information?

*Response*

The Department's regulations do not require reporting to any entity other than the Department or an LMRO.

*Comment*

A clinical laboratory must rely upon information provided by other individuals to comply with the regulations. Information that is not provided to the laboratory when solicited will result in a failure to comply with the regulations. The Department should add the following language "unless due to circumstances beyond the control of the clinical laboratory," to the end of subsection (a).

*Response*

The Department agrees that the clinical laboratory should not be responsible in situations when the solicited information is not forthcoming. The Department has added the recommended language to subsection (a).

*Section 27.7. Cooperation between clinical laboratories and persons who order laboratory tests.*

This section requires laboratories to give a person requesting a laboratory test a form on which information necessary for the laboratory to complete a case report can be provided to the laboratory. The section also requires the person ordering the test to provide the laboratory with the information solicited by the form that the person ordering the test currently has or may readily obtain at the time the test is ordered.

*Comment*

The Department should clarify who "the person requesting the test" is. Is there a difference between the person ordering the test, and the person requesting the test. The Department should use one term or the other. In a long term care setting, the person who orders the test is the doctor, however, a nurse fills out the requisition for the test.

*Response*

Nurses as well as doctors have reporting responsibilities under the act and these regulations. This section, however, does not focus on reporting responsibilities, but, rather, states requirements for what information should be included with the order for the test. The person ordering the test must provide the necessary information to the laboratory so that it, in turn, can fulfill its reporting responsibilities to the Department. If, to do this, the staff of the facility or office must provide information, or fill out the form, then they should do so. It is, however, the responsibility of the person ordering the test to ensure the necessary information is present. In the example presented by the commentator, this would be the doctor who orders the test, not the nurse or other person who prepares the form requesting the test. The Department has changed the regulation to clarify this.

*Comment*

If the laboratory is to provide the appropriate laboratory requisition slips, who is responsible for obtaining them? In a long-term care setting, the long-term care provider contracts with a laboratory for services and has no control over the laboratory. Frequently results are delayed in reporting and real and potential problems in communications exist between the laboratory and the long-term care provider. The regulations should take these concerns into account.

*Response*

The Department has not changed the proposed regulation in response to this comment. The question of who is responsible for obtaining laboratory slips and communications between a laboratory and a health care practitioner should pose no problems in reporting. The health care practitioner or facility required to report is to do so as soon as there is a clinical determination that a reportable disease, infection or condition exists. There is no need to wait for laboratory confirmation of the disease, infection or condition.

*Section 27.8. Criminal penalties for violating the act or this chapter.*

This section reiterates the penalties for violation of the act and regulations included in sections 19 and 20 of the act (35 P. S. §§ 521.19 and 521.20).

*Comment*

This section includes penalties for persons with tuberculosis and other communicable diseases who fail to comply with the act and regulations. These penalties will not serve as a deterrent against leaving facilities, particularly if a person is destitute or homeless. This section is not enforceable, or in the best interests of quality care. A hospital cannot detain these people, and local law enforcement will not take any action.

Further, it is unclear whether these incidents should be brought to the attention of the State or a local health department. The Department should provide guidance about what is to be done when a person leaves a facility against advice.

*Response*

The Department has not changed the proposed regulation to address this comment. This section reiterates penalties for violations of the act and regulations that are contained in sections 19 and 20 of the act. The Secretary of Health is given broad powers to enforce the law and these regulations, particularly the law and regulations relating to quarantine:

> He may issue warrants to any sheriff, constable or policeman to apprehend and arrest such persons who disobey the quarantine orders or regulations of the department of health. Every warrant shall be forthwith executed by the officer to whom directed, who shall make due return of the execution thereof to the [Secretary]. (71 P. S. § 1402).

Although the Department has not in recent history sought imposition of these statutory penalties, and agrees that illness should not be criminalized, it has used the threat of penalties to obtain cooperation from individuals who have been and could continue to be noncompliant with treatment and control measures. This has been done with the cooperation of law enforcement officials, who are required, by law as discussed previously, to cooperate with the Secretary in these matters.

It is not the Department's intention to make the facility responsible for detaining a patient. It is the Department or local health department that is responsible for ensuring patient compliance. If the facility is within the geographic area over which a local health department has jurisdiction, it should call that local health department regarding these incidents. The facility, when in doubt, may always call the Department, which can determine where jurisdiction lies. Intervention by the departments after notification at the earliest possible time of all suspected and confirmed cases of tuberculosis will provide the departments the opportunity to take necessary action, including petitioning courts for aid, if necessary, to detain noncompliant patients. The act gives the Department, or, depending upon the location of the patient, the local health department, the authority to take action when a patient refuses to be tested for a communicable disease, or is noncompliant with the orders of the Department or local health departments regarding the treatment and control of that disease. See sections 7 and 11 of the act (35 P. S. §§ 521.7 and 521.11). When an individual agrees to treatment at a particular facility, or is court-ordered to treatment in a particular facility recommended by the Department, the Department pays the facility according to contracts it has with that facility. The Department has, on occasion, provided funds for security to enforce the quarantine.

*Comment*

There is concern about the extended period of time acute care hospitals are used essentially to house tuberculosis patients that require isolation or are noncompliant. The payer may determine that this is not medically necessary, so that hospitals are not getting reimbursed at the level needed to care for these patients. The Department should develop alternative placement arrangements for patients who no longer require hospital services. The Department should also address reimbursement issues with governmental and commercial payers.

*Response*

As stated previously, with respect to individuals with whom the Department is involved, the Department contracts with facilities for the provision of care at a rate agreed upon in the contract. The Department relies upon its contracted tuberculosis consultant physicians to advise upon the time limitations of the quarantine. Any hospital that does not wish to provide these services need not enter into a contract with the Department. If hospitals are unhappy about third-party reimbursement rates, for example, Medical Assistance rates, hospitals must address those issues with the responsible agencies, not the Department. These regulations are not an appropriate venue for those conversations. If a hospital has an issue with anything done by a local health department with respect to tuberculosis, the issue should be addressed with that health department.

*Comment*

The Department must believe that there is considerable lack of compliance to justify criminal penalties. The regulations must be very specific concerning who is to take what action and how the action is to occur, since failure results in criminal penalties.

*Response*

The Department has not changed the proposed rulemaking to address this comment. The referenced penalties are all taken from the act. The requirements for reporting are carefully defined in the act and regulations. Since most of these requirements have existed for 50 years, compliance should not be difficult. The Department is currently considering how to provide educational sessions for persons who believe a "refresher" course in reporting would be useful.

*Section 27.9. Authorized departures from the regulations.*

The proposed section stated that the Department could decide against enforcing a provision of the regulations when it determines, with the agreement of the Board, that the provision is outdated, and that waiving the provision would be necessary to protect the health of the people of this Commonwealth.

*Comment*

The Department can only amend regulations by promulgating new rulemaking. The Department should add language to state that if the Board affirms, the Department will amend the regulations, or should explain its statutory authority for amending regulations without going through the regulatory process.

*Response*

The Department has not adopted the proposed section. The provision was not intended to allow the Department

to amend its regulations without rulemaking. The Department was only announcing its intention to, upon the approval of the Board, cease enforcing certain regulations that are not parallel to a statutory requirement, when those regulations are outdated.

*Comments*

How does the Department intend to communicate in a timely fashion that it has decided upon an exception?

The regulations do not address the question of what would occur if the Board affirmed or rejected the exception.

The Department removed language similar to this from other parts of the regulations. Did it intend to retain the language regarding exceptions in this section? How is it permissible to grant an exception without regulatory action?

*Response*

Because the Department has chosen not to adopt the proposed section, there is no need to respond to these comments.

*Comment*

The Department should consider incorporating the Morbidity and Mortality Weekly Report (MMWR), which would be a viable alternative toward authorizing an exception, if a regulation becomes outdated. Guidelines for documents that can be incorporated by reference are found in 45 P. S. § 727 (relating to matter not required to be published) and 1 Pa. Code § 3.41 (relating to matter not required to be published).

*Response*

The Department does consider the MMWRs relating to disease prevention and control, as well as other guidelines and recommendations from the Centers for Disease Control and Prevention (CDC) and its Council of State and Territorial Epidemiologists in making decisions concerning what diseases, infections and conditions to add to the list of reportable diseases. The Department is not, however, required by any entity to accept these recommendations and guidelines in their entirety. It is up to the Department, with the approval of the Board, to determine when and how to add diseases, infections and conditions to the list. See 35 P. S. § 521.16(a) and 71 P. S. § 536(a) with respect to the Department's authority to issue rules and regulations on communicable and noncommunicable diseases, declare diseases to be communicable, and to establish regulations for the prevention and control of disease. These decisions must be made on a state-by-state basis, since they depend upon the different populations of the state and their needs, and other characteristics of each state.

*Subchapter B. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS*

*Section 27.21. Reporting of AIDS cases by physicians and hospitals.*

This section states the requirements for physicians and hospitals reporting AIDS.

*Comment*

The Department erred in deleting requirements from its regulations that both hospitals and physicians report cases of AIDS. To only require reporting by physicians could lead to underreporting of AIDS cases.

*Response*

The Department agrees that both hospitals and physicians should report cases of AIDS. The deletion of the requirement relating to hospitals was inadvertent. The section has been revised accordingly.

*Section 27.21a. Reporting of cases by health care practitioners and health care facilities.*

This section lists the diseases, infections and conditions reportable by health care practitioners and health care facilities. This section also provides the time frames in which the disease, infection or condition must be reported.

The Department has made some minor changes to the list from the proposed rulemaking for the sake of accuracy. The Department has changed the term "Legionnaire's disease" to the more technically accurate "Legionellosis." The Department has also deleted yellow fever from the regulations since yellow fever is an arbovirus, and there is no need to list it separately.

*Comment*

Under subsection (b)(1) (now subsection (a)(1)), a health care practitioner or a health care facility is not required to report if that health care facility or practitioner has already reported the case. The Department should clarify that a health care facility is also not required to report if its laboratory has reported previously. Currently, hospitals are not reporting if their laboratories are reporting. If the Department does not agree to this change, it should explain why duplicate reports are necessary, and how the benefits of this reporting outweigh the costs.

*Response*

The Department has not changed the proposed rulemaking in response to this comment. Reporting by practitioners and facilities as well as laboratories, what is referred to as the "dual pathway" of reporting, is not unique to this Commonwealth. It is the National standard for ensuring completeness of reports. Ideally, the practitioner or facility should make the initial case report. Historically, however, there has been significant noncompliance. Through the identification of practitioners and facilities in laboratory reports, the Department is able to contact practitioners and facilities and obtain from them a completed case report on a particular patient whose test result has been reported to the Department by a laboratory but for whom no report has been made by the provider. This approach is consistent with the CDC protocols and with protocols in other states. A more detailed explanation of why reporting from all possible reporting entities is necessary for a successful disease prevention and control program has been provided in the Department's response to general comments concerning reporting.

*Comment*

The Department's need for potentially overlapping information from facilities, practitioner, clinical laboratories and persons in charge of group facilities is unclear.

*Response*

The Department has not changed the proposed regulation in response to this comment. The Department is seeking overlapping information from providers, facilities and the public, to ensure that it obtains the widest variety and amount of information possible. The need for all relevant and available information, and the manner in which the Department resolves duplicate reports, has been discussed.

*Comment*

Does this section supersede § 211.1 (relating to reportable diseases in long-term care nursing facilities)?

*Response*

Section 211.1 is based on the requirements of this chapter. By this rulemaking, the Department is also amending § 211.1 to state that reportable diseases, infections and conditions are those diseases, infections and conditions listed in this section. The reporting requirements in § 211.1 do not eliminate the reporting requirements for a health care facility under Chapter 27.

*Comment*

The Department should move the following diseases from subsection (a)(2) (now subsection (b)(2)) which contains a listing of all diseases infections and conditions to be reported within 5 days, to subsection (a)(1) (now subsection (b)(1)) which contains a list of all diseases infections and conditions to be reported within 24 hours: animal bite, anthrax, arbovirus disease, enterohermorrhagic E. coli and legionellosis. With these diseases and conditions, action must be taken to prevent serious consequences to the individual within a shorter time frame than 5 days. With respect to anthrax, since there is the possibility of a bioterrorist attack using this disease as a weapon, it should be reported within a shorter time frame than 5 days.

*Response*

The Department agrees with the comments, and has moved these diseases and conditions from the list requiring reporting within 5 days to the list requiring reporting within 24 hours. See subsection (b)(1) and (2).

*Comment*

The Department should add the following diseases to the list of diseases that must be reported within 5 days: Creutzfeldt-Jakob disease; streptococcus pneumoniae drug resistant invasive disease; and staphylococcus aureus, Vancomycin-resistant (or intermediate) invasive disease.

This comment also applies to § 27.22 (relating to reporting of cases by clinical laboratories).

*Response*

The Department agrees with the comment, and has added these diseases to the list of diseases that must be reported within 5 days. See subsection (b)(2). That action is consistent with National reporting standards recommended by the CDC.

The Department has made similar revisions to § 27.22(b).

*Comment*

There is a concern that this section would require emergency management technicians (EMTs) to report cancer. While this would not include patients already diagnosed, it could be confusing to EMTs who do not know the complete history of the patient. Further, EMTs cannot diagnose cancer.

*Response*

It was not the Department's intention to require health care practitioners to perform diagnoses who cannot, within the scope of their licensure or training, diagnose diseases, infections or conditions. The diseases, infections and conditions listed in subsection (b), (proposed as subsection (a)), are only to be reported in accordance with subsection (a), (proposed as subsection (b)), and the remainder of the chapter. Cancer, which only certain specified health care practitioners and facilities are required to report (see § 27.31 (related to reporting cases of cancer)), would not be reportable by EMTs. Because this section has generated some confusion among commentators, the Department has rearranged subsections (a) and (b), and added language to clarify that if there are specific requirements in other sections for the reporting of certain diseases, those provisions must be read in addition to this section.

Further, the Department has added language to subsection (d) to clarify that health care practitioners as well as health care facilities are to look to § 27.31 (relating to reporting cases of cancer) to determine how to report cancer cases. The Department has also attempted to provide additional clarity by adding subsection (a)(4), as well as similar language to § 27.31(a) and (b), which states that only those facilities and practitioners actually providing services relating to the individual's cancer are required to report the case as a cancer case.

The Department has also revised the language in this section that requires reporting of identified diseases, infections and conditions to clarify the meaning of the word "identify." A disease, infection or condition is reportable when it has been identified by symptoms, appearance of the individual or diagnosis. Consequently, a diagnosis is not needed to trigger a duty to report.

*Comment*

While Haemophilus influenzae should be reportable within 24 hours, the Department should delete the reference to "type B invasive disease" from the list of reportable matters. Many clinical laboratories do not conduct serotyping, and laboratories that do conduct serotyping may not have results for several days. Since action may need to be taken sooner than it would take the laboratory to conduct the serotyping, the Department should make Haemphilis influenzae reportable within 24 hours. This comment pertains to § 27.22(b)(1) as well.

*Response*

The Department agrees with this comment, and is deleting "type B" from the reference to Haemophilus influenzae in subsection (b), (proposed as subsection (a)).

*Comment*

All types of hepatitis should be reported, and should be reportable within 5 days of identification of the disease.

*Response*

The Department agrees that all forms of hepatitis should be reportable, and has revised the regulations to make hepatitis reportable within 5 days of the identification of the disease. The Department has divided reportable diseases into two categories, those reportable within 24 hours, and those reportable within 5 days, to eliminate some burden from those entities required to report. Only those diseases that need quick public health intervention are required to be reported within a 24-hour period. The Department agrees that hepatitis does not need to be reported within that time frame due to the manner of its transmission.

*Comment*

The regulation should require the reporting of chronic cases of hepatitis C as well as acute cases. More extensive reporting of hepatitis C cases is necessary so that reputable and inclusive data can be used to make an accurate assessment of the public health threat of hepatitis C to citizens of this Commonwealth. This issue should not be allowed to languish through a long regulatory process. This same comment is applicable to §§ 27.22 and 27.43a (relating to reporting of cases by clinical laboratories; and reporting by LMRO of outbreaks and selected diseases).

*Response*

The Department has added language to the regulation to clarify that it is requiring the reporting of all cases of hepatitis C, chronic as well as acute. The Department looks at all reported cases of hepatitis C to resolve whether an individual is an acute or chronic case. It makes this assessment by determining whether the individual also has clinical symptoms. An individual who has both a positive laboratory serology and presents with clinical symptoms is an acute case. An individual whose laboratory tests show that he is positive for hepatitis C, but who has no clinical symptoms, is a chronic case. Since an intervention message can be life-saving for persons with chronic hepatitis C, information regarding the need to practice safe sex and to get vaccinated for hepatitis A and B as well as other information relating to the disease will be given by the Department to each individual reported with hepatitis C.

*Comment*

The Department should delete hepatitis, viral, including type A and type E, from proposed subsection (a)(1) (now subsection (b)(1)) which requires reporting within 24 hours. All other types of hepatitis are reportable within 5 days. References to type G should be deleted from the proposed subsection (a)(2) (now subsection (b)(2)) listing of diseases reportable within 5 days, since it does not exist. Hepatitis, non-A and non-B should be added to the 5 day list in proposed subsection (a)(2). These same comments apply to § 27.22(b).

*Response*

The Department agrees with the comments, and has revised the references to hepatitis in this section. The Department has deleted all references to hepatitis from what is now subsection (b)(1), which requires reporting within 24 hours. The regulations require that hepatitis, viral, all types, is reportable within 5 days of its identification by symptom, patient appearance or diagnosis. See subsection (b)(2).

The Department has made similar revisions to § 27.22(b).

*Comment*

The Department should require HIV reporting. The Legislature contemplated reporting of HIV infection under section 7(a)(9) of the Confidentiality of HIV-Related Information Act (35 P. S. § 7607(a)(9)). The Department should also explain what type of HIV reporting it favors; most persons appear to favor a unique identifier system of reporting.

*Response*

The Department has chosen to promulgate regulations relating to HIV separately. The revisions to Chapter 27 included in this final-form rulemaking have been under consideration by the Department and various stakeholder groups for the past 10 years. The Department was anxious to proceed with the amendments, and did not wish to delay them while important consideration and public discussion was given to the question of when and how HIV should be made reportable. The Department neither wished to rush the process involving the promulgation of regulations relating to HIV reporting, nor to delay this general rulemaking concerning communicable and noncommunicable diseases.

Further, the importance of the promulgation of regulations relating to HIV reporting warranted a separate rulemaking so that attention could be focused on that issue. Therefore, the Department has proposed separate regulations on that topic. The regulations that would require reporting of certain HIV tests, CD4 T-lymphocyte counts below certain levels, and perinatal exposure of newborns to HIV by name, were published as proposed at 31 Pa.B. 2126 (April 21, 2001). A 30-day public comment period was provided.

*Comment*

With respect to the requirements for reporting phenylketonuria, MSUD, hypothyroidism and sickle cell hemoglobinopathies, the Department should explain why it is using both the phrase "up to 5 years" and "up to 60 months" in relation to the age of the child in whom the disease should be reported.

*Response*

The Department agrees that this language should be changed, and is revising the regulation to state that these diseases are reportable in children under 5 years of age.

*Comment*

The Department should include smallpox in the list of diseases that must be reported within 24 hours. The threat of bioterrorism requires the reintroduction of smallpox into the list.

*Response*

The Department agrees with the recommendation, and has added smallpox to subsection (b)(1).

*Comment*

The statement in the preamble to the proposed regulations that it is not clear that chickenpox can be prevented by vaccination is outdated. This vaccine is now recommended universally for children and other persons not known to be immune.

*Response*

The Department agrees that the statement is no longer correct. The Department has promulgated regulations that include chickenpox (varicella) in the list of diseases for which immunization is required for school entry and attendance. These provisions will be effective for the 2002-2003 school year.

*Comment*

Does the Department distinguish between occurrence of the chickenpox disease and postvaccination cases?

*Response*

The Department does not distinguish between wild virus chickenpox and postvaccination cases.

*Comment*

The Department should remove required reporting of chickenpox (varicella) until it decides that reporting is warranted based on trends in information reported by clinical laboratories. The 3-year time frame presupposes that cases will need to be reported by health care facilities and practitioners. The Department should wait until chickenpox (varicella) immunity is required in schools.

*Response*

The Department has not changed the proposed rulemaking in response to this comment. The Department believes that reporting of varicella is warranted now. As stated previously, the Department's regulations requiring immunity from chickenpox as a condition of school entry and in the seventh grade will be in place for the beginning of the 2002-2003 school year.

*Comment*

Chickenpox (varicella) should be added to the list of reportable diseases, however, there should not be a 3-year delay for reporting by practitioners. Laboratories will not have data to provide, since a primary care provider rarely, if ever, requires a laboratory test for the disease. School nurses and child care programs could report the disease, since often only the most severe cases are seen by physicians.

*Response*

The Department has not changed the proposed rulemaking in response to this comment. Laboratories are already reporting this disease on a voluntary basis. Sentinel surveillance systems are already ongoing in schools and day care centers, and with physicians. Sentinel surveillance for varicella involves polling approximately 2,000 sites Statewide on a monthly basis to gather information on ongoing incidence, morbidity and mortality of varicella. As varicella vaccine usage increases, the Department will monitor disease incidence using this system until the numbers of cases of varicella are at a more manageable level for individual case reporting. The Department anticipates that this will be within a 3-year period from the effective date of these regulations, which will coincide with a 3-year period from the effective date of the varicella immunization requirements. The Department, in setting a 3-year delay in reporting for health care practitioners (which includes school nurses) is attempting to alleviate what could become a burden for health care practitioners, and what could, if reporting were immediately required, cause them to have to report tens of thousands of cases a year. The Department's expectation is that within 3 years of the regulations regarding school immunizations and immunity being in place, this number will drop to less than 1,000 annually.

*Comment*

The Department should add to subsection (c) a requirement that a child care group setting that enrolls more than 12 children is to report to the LMRO any unusual increase in the number of absentees.

*Response*

The Department agrees that such a requirement would aid it in its responsibilities to prevent and control the spread of disease, and has added the recommended language to subsection (c).

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

This section addresses reporting requirements for clinical laboratories. It includes the list of diseases, infections and conditions reportable by laboratories and the time frames in which laboratories are required to report.

*Comment*

The Department should delete language from the regulation that limits the reporting of arboviruses to the Eastern, Western and St. Louis arboviruses. The Department should add references to West Nile and Equine as well. Arboviruses can appear in unexpected places, as the West Nile outbreak in New York City shows. Any arboviral case could lead to the need for mosquito control efforts and other public actions.

*Response*

The Department agrees with the comment. Since the Department's intention is to require the widest reporting possible, it has deleted all references limiting reporting to certain types of arboviral diseases, thereby requiring the reporting of all arboviruses.

*Comment*

The Department should add language that would permit either the referring laboratory or the laboratory performing the test to report the results. This would ensure that the Department receives a report that contains the most complete information. It will also eliminate duplication. The referral laboratory may not have all the demographic information requested by the Department. If the Department chooses not to revise this section, it should explain why duplicate reports are necessary and how the benefits outweigh the costs.

*Response*

The Department has not changed the proposed rulemaking in response to this comment. Because the Department needs all the information on a case it can obtain, both the "primary" and the "referral" laboratory are required to report. The necessity for reporting from all possible reporters has already been discussed in detail.

*Comment*

The Department should explain why it has made decisions to delete or add specific diseases.

*Response*

The Department will respond to this comment in its responses on the specific requests for additions or deletions to the list of cases reportable by clinical laboratories.

*Comment*

The Department should add CD4 T-lymphocyte counts of 500 cells per microliter or less to the list of reportable diseases in subsection (b).

*Response*

The Department has not added this requirement to these regulations. The Department, in a separate rulemaking, published at 31 Pa.B. 2126 is proposing to add a requirement for reporting of laboratories, practitioners, and other entities of CD4 T-lymphocyte cell counts of less than 200 cells per microliter or which are 14% or less of total T-lymphocyte cells. Chapter 27 will be amended again when the Department acts to adopt that proposed rulemaking.

The Department has not proposed the reporting of CD4 T-lymphocyte cell counts of less than 500 cells per microliter because there is not a National consensus on reporting at that level.

*Comment*

The Department should add the following diseases to the list of diseases reportable by laboratories: cryptosporidiosis; histoplasmosis; meningitis; toxoplasmosis and yellow fever. Arboviruses should be listed in the same manner as in § 27.21a.

*Response*

The Department agrees and has amended this section to require reporting of cryptosporidiosis, histoplasmosis and toxoplasmosis by laboratories. This comports with the National standard for reporting.

The Department has revised the reference to arboviruses in this section to require reporting of all arboviruses, as it has in § 27.21a(b)(1). Since yellow fever is a mosquito-borne disease, and is covered by the term "arbovirus," there is no need to add it specifically to the list. Similarly, the regulation requires the reporting of meningococcal infections by laboratories, rather than meningitis. Meningitis is a clinical diagnosis, and is

required to be reported by health care practitioners and health care facilities in § 27.21a.

*Comment*

The Department should delete synctial virus from the list of diseases required to be reported by clinical laboratories. Local health authorities will be inundated with reports, and the Department did not provide a reason in its preamble to proposed rulemaking for including this disease.

*Response*

The Department has not changed the proposed regulation in response to this comment. Since this section requires reporting of synctial virus by laboratories, and not by health care practitioners and facilities, the Department does not expect to be inundated by reports. This requirement will allow the Department to identify outbreaks of disease once the use of the new vaccine for this virus is widespread.

*Comment*

The Department should remove references to unusual clusters of isolates from subsection (b) since the term "unusual" may mean something different depending on the disease.

*Response*

The Department has not changed the proposed regulation in response to this comment. The term "unusual" may mean different things depending on different diseases. For example, a laboratory may notice that it has positive results for E. coli 0157:H7 from tests on several different specimens, and this does not usually occur. This unusual grouping of test results could be indicative of an outbreak. The Department does not want to lose an opportunity to intervene to prevent and control the spread of disease.

*Comment*

The Department should add the following language to subsection (c): "the report shall include the source of the specimen (such as, serum, CSF, stool, wound); the results; the range of normal values for the specific tests."

*Response*

The Department agrees that this additional information would be valuable to it in its disease prevention and control function. It has added the recommended language to subsection (c), with the exception of the test results, since that data element is already included in the regulation.

*Comment*

The Department should adopt a unique identifier system for all reporting. There is a concern with respect to the confidentiality of information reported to the Department, particularly with cancer information and lead test results. A unique identifier system would permit the Department to carry out its responsibilities while protecting the information.

*Response*

The Department has not changed the proposed rulemaking to address this comment. The Department cannot fulfill its disease prevention and control functions, which include follow up with individuals to ensure that medication is being taken, treatment being followed and contacts being notified, without obtaining the name and identifying information of the individual about whom the report is made. The Department has had information reported to it under the act since 1955 by name of the individual without major issues surrounding confidentiality.

The act requires the Department and local health departments to keep confidential the information they collect under the act. The act prohibits the Department from releasing information secured under the statute, even in the face of a subpoena, with few exceptions. Section 15 of the act (35 P. S. § 521.15) provides as follows:

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

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

Because the Department and local health departments take the responsibility to protect all information reported under the act very seriously, they have, on several occasions, engaged in litigation in State and Federal court to prevent the release of information reported under the act. The Department has no reason to abdicate this responsibility to maintain the confidentiality of this information.

With respect to cancer reporting, this type and level of cancer reporting is required by the Federal Cancer Registries Amendment Act of 1992.

*Comment*

Subsections (d), (e) and (k), which require reporting of diseases and conditions of the newborn, sexually transmitted diseases (STDs), lead levels and tuberculosis test results to separate places within the Department (and in the case of tuberculosis, to Allegheny and Philadelphia Counties when the patient resides there), should be deleted. All reports should be made to a single location within the Department.

*Response*

The Department agrees that a single reporting location should be developed for electronic laboratory reporting, but is unwilling to do so for paper reporting at this time. The Department is, therefore requiring that all laboratory reports that are made electronically be made to the Department's Division of Infectious Disease Epidemiology, with the exception of newborn screening, lead and cancer. The Department intends to phase in electronic reporting by all reporters as has already been discussed.

The Department is addressing paper reporting by changing the requirement in subsection (e) that laboratories making paper reports send the report to the county or municipal department of health where the patient resides. Section subsection (d) now requires the laboratory to send paper reports to the LMRO where the case

was diagnosed or identified. This is in keeping with the Department's revisions to requirements for health care providers and practitioners who report on paper. The Department has, therefore, deleted proposed subsection (k), which would have required laboratories to report tuberculosis to either Philadelphia or Allegheny County, depending upon where the case resided, or as a default, to the Division of Tuberculosis and Sexually Transmitted Diseases.

The Department has also made changes to § 27.33 (relating to reporting cases of sexually transmitted diseases). The Department has revised that section to delete special reporting requirements for syphilis, and to require paper reports of sexually transmitted diseases to be sent to the LMRO where the case is diagnosed or identified (see § 27.33(b)) and electronic reports to be sent to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology (see § 27.33(c)). The Department has deleted the reference to § 27.33 from subsection (e).

*Comment*

The Department should add language that would require laboratories that cannot perform serotyping to mail isolates of salmonella (subsection (f)), Neisseria meningitides (subsection (g)), E. coli isolates (subsection (h)), and H. influenzae isolates (subsection (i)) to the Department. All other laboratories should be exempted from that requirement as they can conduct the serotyping themselves. This would eliminate the need to send a potentially biohazardous specimen through the mail.

*Response*

The Department has not changed the proposed regulation in response to this comment. The only laboratories that can perform the level of serotyping required by the Department for its disease investigation and surveillance are National reference laboratories, which obtain the necessary reagents from the CDC to perform this testing. However, a commercial National reference laboratory may not be able to perform all the required tests on the specimen. The only laboratory within this Commonwealth that can perform the level of serotyping needed by the Department to conduct its disease surveillance and investigation is the Department's State laboratory operated by its Bureau of Laboratories. The Bureau of Laboratories also maintains the isolates so that the Department can match up disease strains and pinpoint outbreak sources. This enables the Department to control the spread of the disease. Further, the Department does not charge the person submitting the specimen; it does this testing as a public health service.

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

This section requires individuals in charge of certain types of group facilities to report diseases, infections and conditions.

*Comment*

The language of this section appears to require the same level of reporting for persons in charge of group facilities as is required of health care practitioners and health care facilities. Individuals in charge of group facilities do not diagnose, or treat or examine patients. Does this section intend schools and child care providers to become mini health clinics? What does the Department expect from layperson's reports? Can reports be based on symptoms and suspicions, rather than identification?

*Response*

As the Department has explained in response to comments on § 27.21a, the Department does not intend to require diagnosis of a disease, infection or condition by those individuals who are not, by training and experience, capable of performing diagnoses, or who are not, by the scope of their licensure, permitted to diagnose. The act and regulations require reporting, not only of a diagnosed case, but also of a suspected case, based on symptoms, appearance and the circumstances surrounding the suspected case. The Department does not expect a layperson to be as aware of diseases, infections and conditions as a health care practitioner or facility, and has changed the language of this section to clarify that. The Department has explained how reports from laypersons are handled in its response to comments on the definition of the term "health care practitioner" in § 27.1.

*Comment*

Why is the phrase, "except as otherwise set forth in this section" needed here?

*Response*

The phrase was included because the section, as proposed, would have required individuals in charge of certain group facilities to report in the same manner as health care practitioners are required to report under § 27.21a. Some of the diseases listed in § 27.21a are reported in a unique manner, however. Lead poisoning, for example, is reported directly to the Division of Maternal and Child Health, rather than to an LMRO. Because the Department has revised this section by deleting the statement that reports are to be made in accordance with § 27.21a, the phrase is no longer necessary. The Department has deleted it from the regulation.

*Section 27.25. (Reserved).*

This section, which is being deleted by the Department, required licensed health care practitioners other than physicians, including nurses, chiropractors and optometrists, to report the knowledge or suspicion of a communicable disease.

*Comment*

The Department states that it is deleting this section because it is including the requirements of the section in § 27.21a. The regulations do not say who is to report. This should be clarified.

*Response*

Section 27.21a clearly states that health care practitioners and health care facilities are to report the listed diseases, infections and conditions. The Department has defined "health care practitioner" broadly to include the individuals listed in repealed § 27.25. The Department believes that no further clarification is necessary, and has deleted the regulation, as proposed.

*Section 27.30. Reporting cases of certain diseases in the newborn child.*

This section requires that reports of MSUD, PKU, primary congenital hypothyroidism and sickle cell hemoglobinopathies be made to the Department's Division of Maternal and Child Health.

*Comment*

This section should be deleted, since all reports should be made to one central location within the Department.

*Response*

The Department has discussed the issue of reporting to a central location in its response to general comments on

the reporting of cases. However, when electronic reporting for practitioners and facilities as well as laboratories is instituted, § 27.30 is unlikely to be repealed. There are additional considerations with respect to reporting results of metabolic disease testing in the newborn that necessitate continued reporting of these diseases directly to the Division of Maternal and Child Health. If these diseases were reported to a central location within the Department, that location would have to sort these reports out of reports of each of the 52 reportable diseases, infections and conditions, and route them to the Division of Maternal and Child Health. The delay in time that this would cause could be dangerous for the children involved. There is a need for speed in reporting these diseases to the Division, which is responsible for follow-up and referral of children with these conditions. MSUD, for example, within the space of 7 days, can cause severe mental retardation or death.

*Comment*

Expanding reporting to the four diseases included in the regulations, MSUD, PKU, sickle cell hemoglobinopathies and congenital hypothyroidism is supported, however the regulation should be expanded to include all diseases for which tests are conducted by Neogen, Inc., a company offering an expanded testing panel which is currently used by most birthing hospitals. It is in the epidemiological interest of the Department to monitor the frequency of these diseases for their possible addition to the newborn screening program.

*Response*

The Department has not changed the proposed rulemaking in response to this comment. The expansion of diseases and disorders reported to the Department's newborn screening program is cautiously and carefully considered on a condition-by-condition basis, based on criteria adopted by the Department and recommended by the Council of Regional Networks for Genetic Services. Before adding diseases and conditions to the list, the Department considers demographic information, the genetic composition of the population, available methodologies, outcomes and economics. The Department will screen for only those conditions for which effective intervention and treatment is available and accessible to all affected newborns. The Department also considers the impact of the required reporting on the program's capacity for follow-up and treatment. A follow-up system must be in place, or able to be put in place, that will ensure that any positive or potentially positive result for a newborn is pursued through to resolution.

The Department does continually review the newborn screening program and the list of diseases and conditions included in that program, and evaluates the need for expansion. At 31 Pa.B. 2271 (April 28, 2001), the Department published proposed rulemaking in which it proposed to add two conditions to the list—galactosemia and congenital adrenal hyperplasia. That rulemaking, upon becoming final, will amend these regulations relating to communicable and noncommunicable diseases as well, to add the two conditions to the list of reportable diseases, infections and conditions. Questions concerning the appropriateness of including diseases and conditions on the list of diseases and conditions for which newborn screening is done are more appropriately addressed through discussion on that rulemaking.

*Section 27.32. (Reserved).*

This section, which is being deleted, required reporting of AIDS by hospitals and physicians.

*Comment*

The Department should not delete the section, which includes the requirement that AIDS be reported by hospitals, health care facilities and institutions. Hospitals as well as health care practitioners should be required to report AIDS.

*Response*

As the Department has stated earlier in its response to comments on proposed § 27.21, the deletion of a requirement that hospitals report cases of AIDS was an oversight, and the Department has reinstated that requirement in § 27.21. The Department's regulations never required that institutions report AIDS.

*§ 27.33. Reporting cases of sexually transmitted disease.*

This section specifies how health care practitioners and health care facilities are to report cases of sexually transmitted diseases.

This section has been revised in response to general comments that all diseases, infections and conditions should be reported in the location where the individual is, rather than where the individual resides. The Department has changed this section to require that all reports of sexually transmitted diseases be made to the LMRO where the case is diagnosed or identified. This will simplify disease reporting.

*Section 27.34. Reporting cases of lead poisoning.*

This section includes specific requirements for reporting cases of lead poisoning. The Department has changed the language of the section to clarify its intent that clinical laboratories report elevated blood lead levels (not lead poisoning) as defined by the NIOSH, in persons 16 years of age or older. Currently, that definition is a venous blood lead level of 25 micrograms per deciliter (µg/dL) or higher. The Department will publish updates of this definition in the *Pennsylvania Bulletin* within 30 days of its notification by NIOSH. See § 27.34(a)(3).

*Comment*

Reporting of all childhood lead testing analyzed by a clinical laboratory, regardless of the result, is supported. This will give the Department sufficient information to develop appropriate lead testing protocols for this Commonwealth. Reporting by the laboratory is also supported, since all venous and capillary lead testing is done by laboratories.

*Response*

The Department agrees.

*Comment*

The requirement that a clinical laboratory report blood lead tests performed on pregnant women should be deleted from subsection (a). A laboratory has no way of knowing whether a specimen for testing is from a pregnant woman. This information is more appropriately reported by health care practitioners, who have access to it.

*Response*

The Department agrees, and has changed subsection (a) to remove the proposed requirement that clinical laboratories report blood lead results on pregnant women. The Department has included in subsection (a) all requirements for clinical laboratories, and has revised subsection (b) to require health care practitioners and health care facilities to make reports on blood lead levels in pregnant women, since these entities would have access to that

information. Subsection (b) also requires that health care practitioners and health care facilities report all blood lead levels, both venous and capillary, on persons under 16 years of age.

*Comment*

As with newborn screening reporting, all reports of lead poisoning should be sent to one clearinghouse within the Department. This would make it easier for persons and facilities required to report.

*Response*

The Department has not changed the proposed regulation to address this comment. The Department has addressed the issue of reporting to a central location in its response to general comments on these regulations. Further, the Department currently has in place, and is refining, an electronic system for reporting blood lead levels. When, in the development of its electronic disease surveillance system, the Department finds that it is more efficient and cost effective to include lead reporting within that system, the Department will do so upon 6 months notice to reporters. See § 27.4(b).

*Comment*

In subsection (a), the Department uses the term "persons under 16 years of age" rather than the term "child," which includes anyone 15 years of age and under. The Department should use the term "child" in this regulation.

*Response*

The Department has not changed the proposed regulation to address this comment. Because the Department has revised the definition of the word "child" to include persons under 18 years of age, use of the word "child" in this section, without any qualifying language, would not be accurate. According to the CDC protocols, reportable lead levels for persons under 16 years of age, and for pregnant women, differ from those reportable for persons 16 and older. This is because the susceptibility to lead poisoning is different in persons of different ages, and lead poisoning is an extreme hazard for pregnant women.

*Comments*

Subsection (e) provides for referral of a physician under whose authorization blood is collected for a blood lead test to the appropriate licensing board for disciplinary action if the physician fails to provide the necessary demographic information to the laboratory along with the specimen. This subsection is a cause for concern, and should be deleted.

Subsection (h) should be deleted. Subsection (h) requires that a clinical laboratory follow certain procedures to attempt to obtain information necessary for the laboratory's report to the Department when certain information is not included with the specimen. The laboratory has the responsibility to provide a submission form to the person ordering the test that solicits certain information. The responsibility for providing that information belongs to the person ordering the test. Because there are criminal penalties associated with failure to properly report information, as well as the possibility of licensure sanctions, including revocation of a license, a laboratory should not be required to follow the burdensome procedures included in this subsection.

*Response*

The Department has reconsidered proposed subsections (h) and (i), and has decided that, as proposed, they would place too great a burden upon the clinical laboratory to obtain information from the specimen submitter. It has deleted those proposed subsections. Proposed subsection (e) would have been redundant since, if a physician fails to comply with the regulations on an ongoing basis, the Department may choose to refer the physician for disciplinary action under § 27.6. The Department has deleted proposed subsection (e) as well.

*Comment*

Subsection (i) requires the laboratory to notify the Department of its inability to obtain information from the specimen submitter as required in subsection (h), and includes in paragraphs (1)—(5) the information the laboratory must provide to the Department with this notice. Paragraph (5) requires the laboratory to provide any other information requested by the Department. This paragraph should be limited to any other information necessary to complete the reporting form.

*Response*

Since the Department has deleted proposed subsections (h) and (i), no further response to this comment is necessary.

*Comment*

Subsection (j) provides that a laboratory may be subject to revocation of its license for failure to comply with the subsection, or may be subject to other disciplinary action. To what other disciplinary action does this refer?

*Response*

Because § 27.6 adequately addresses these issues, the Department has deleted proposed subsection (j) as redundant. Under § 27.6, a clinical laboratory that fails to comply with these regulations may be subject to restrictions being placed upon its permit to operate, or revocation of its license under the Clinical Laboratory Act (35 P. S. §§ 2151—2165). Further, a laboratory that fails to comply with the act and regulations may be subject to penalties in accordance with section 20 of the act (35 P. S. § 521.20) and § 27.8.

*§ 27.41a. Reporting by local morbidity reporting offices of case reports received.*

*§ 27.42a. Reporting by local morbidity reporting offices of completed case investigations.*

These sections explain how LMROs are to report.

The Department has revised the proposed sections to reflect its changes to the proposed definition of "LMRO."

*Section 27.43a. Reporting by local morbidity reporting offices of outbreaks and selected diseases.*

This section explains how LMROs are to report. The Department has also revised this section to reflect its changes to the proposed definition of "LMRO."

*Comment*

The Department should review this section, and explain why various diseases have and have not been included in the section.

*Response*

The Department will address this comment in its response to comments on particular diseases.

*Comment*

There is no subsection (a) in this section, therefore, the Department should label subsection (b) as subsection (a).

*Response*

The commentator misread the proposed regulation. The section, as proposed, does include a subsection (a). There is no need to relabel subsection (b) as subsection (a).

*Comment*

Proposed subsection (b)(2) requires that the LMRO report cases of certain diseases, infections and conditions to the Department on the same day any of the listed diseases are reported to it or it finds out about those diseases. The Department should delete hepatitis A and meningitis from subsection (b)(2) and should add the words "food borne" before the word "botulism" in that subsection.

*Response*

The Department agrees with this comment, and has made the recommended changes. An urgent response to reports of hepatitis A and meningitis is not necessary due to the manner in which these diseases are transmitted.

*Comment*

The Department should add the following diseases, infections and conditions to subsection (b)(2): arbovirus disease, haemophilus influenzae invasive disease in a child under the age of 15 years, and Legionnaire's disease. Because of the serious nature of these diseases, action to intervene must be taken to prevent and control their spread in less than 5 days.

*Response*

The Department agrees with this comment, and has revised subsection (b)(2) to include the recommended changes.

*Comment*

The Department should add smallpox to subsection (b)(2) due to the possibility of its use in a terrorist attack.

*Response*

The Department agrees with this comment, and has revised subsection (b)(2) to include smallpox.

*Subchapter C. QUARANTINE AND ISOLATION*

*Comment*

The Department should clarify in the preamble how this subchapter applies to hospitals, or state in its regulations the circumstances under which health care facilities are required to contact local health officials to confer about matters relating to quarantine and isolation. Hospitals routinely adhere to standards relating to isolation of patients and transporting them without notifying the Department or local health authorities. The Department does not need to have routine matters reported to it by health care facilities.

*Response*

Subchapter C has been in place in the form now being amended since 1979. Section 27.67 (relating to movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department) has, over the last 20 or more years, required a health care facility to secure the permission of a local health authority or the Department before moving a person under isolation or quarantine. The only substantive change to this section is to include movement of animals under isolation or quarantine to its requirements, which should have little impact on hospitals. The remainder of the amendments to this section are intended to update the terms used in the section, for example, changing "local health officer" to "local health authority."

There is no need to clarify this subchapter. By law, the Department and local health departments are given broad authority by the General Assembly through the act to prevent and control the spread of disease. See 35 P. S. § 521.3 (relating to responsibility for disease prevention and control). This includes the imposition of disease control measures, including isolation and quarantine, and the ability to set requirements for those control measures, necessary to prevent and control the spread of disease. See 35 P. S. §§ 521.5, 521.7, 521.11 and 521.16(a)(3)(4) and (5) (relating to control measures; examination and diagnosis of persons suspected of being infected with venereal disease, tuberculosis, or any other communicable disease, or being a carrier; persons refusing to submit to treatment for venereal diseases, tuberculosis or any other communicable disease; and rules and regulations); see also 71 P. S. § 536(b) (providing the Department authority to establish and enforce quarantines to prevent the spread of disease) and 71 P. S. § 541(b) (providing the Department through the Board the ability to promulgate regulations for the health and protection of the people of the Commonwealth)).

While the Department recognizes that a health care facility has the responsibility for the individual patient, the Department has the responsibility for the safety and welfare of the entire public. It is necessary for the Department to be involved in matters relating to isolation and quarantine of persons with reportable diseases, regardless of whether these persons are currently in a health care facility, to ensure that the public's safety is considered as well as the patient's. Further, the Department has expertise in these matters which could benefit the health care facility.

If a disease, infection or condition is reportable under these regulations, the health care facility must report it as required under the regulations. The health care facility has no discretion in the matter. This requirement has also not changed over the years, although the list of diseases and the method of reporting may have changed somewhat. If the disease is one which requires isolation of the case or quarantine of the contacts, and the Department or a local health authority orders the isolation or quarantine, the health care facility must comply with the regulations and the Department or local health authority's orders regarding control measures, if any are issued, or be in violation of the law. The Department will, of course, be cognizant of the expertise of the hospital's infectious disease staff, and will work with them to ensure that proper control measures are taken, as it currently does.

*Section 27.60. Disease control measures.*

This section lists the disease control measures that the Department or a local health authority may take, including any disease control measure that the Department or a local health authority considers to be appropriate for the surveillance of disease, when it is necessary to protect the public health. Actions of local health authorities that are not LMROs are conditioned upon the approval of the Department.

*Comment*

There is considerable controversy over the appropriateness and need for isolation of some infections. Many reports and articles provide a different approach for different facilities. There is concern that a long-term care facility may find itself in conflict with the regulations,

and be forced to accept the Department's interpretation of whether isolation was indicated, where and how much. Specifically the concern is with Methicillin resistant staphylococcus aureus (MRSA) and Vancomycin resistant enterococchi (VRE), which are not often seen. It should be assumed that the requirements for disease control measures with respect to these diseases do not apply, since they are not reportable diseases and conditions. Also, a long-term care facility may isolate a salmonella case, but not always with the practice of universal standard precautions.

The Department's statement that it has the discretion to implement the most appropriate disease control measures for the situation is not accurate. This statement gives all the authority to the Department to determine the isolation requirements without any recognition of a facility's systems. The long-term care industry is currently burdened with Department-imposed two-step tuberculin skin testing for all employees. Neither the CDC nor OSHA imposes this requirement. Since the Department is not reasonable with respect to these requirements, long-term care facilities have no confidence that the Department will be reasonable with respect to control requirements. The Department must give some recognition in this section for a health care facility's existing and regulatorily required infection control systems to prevent the future imposition of arbitrary and capricious measures.

*Response*

As discussed in response to general comments on this subchapter, the Department has statutory authority, regardless of existing systems within a health care facility, to require specific disease prevention and control measures as the Department's disease control experts find necessary to protect the fragile population resident in long-term care facilities. The Department and local health departments will work first within a facility's existing infection control systems, which should be adequate for most outbreaks and cases. If, however, additional precautions are necessary, the facility must comply with the Department's orders to remain compliant with the law.

With respect to MRSA and VRE mentioned by the commentator, although these diseases are not specifically listed as reportable within Chapter 27, if there is an outbreak of either, the outbreak is reportable. Upon being informed of the outbreak, the Department may take the steps it deems necessary to prevent and control the spread of disease. Further, these diseases are reportable under the Department's regulations relating to long-term care nursing facilities. See § 211.1(c).

With respect to the issue regarding tuberculosis, the regulations of the Division of Nursing Care Facilities are not in conflict with the recommendations of the CDC. The regulations require a two-step PPD testing procedure, as the CDC recommends. In interpreting its regulations, the Department requires that long-term care facilities have policies and procedures in place to address individual situations, which may satisfy the two-step PPD test requirement. If a long-term care facility has implemented appropriate policies and procedures and the facility's Medical Director is willing to document that a complete two-step PPD test is not required for an individual employee, the Department will consider that when determining if the facility has met the regulatory requirements. Accordingly, the Department is not in conflict with CDC recommendations, but merely requires that each situation be addressed individually by a medical professional to assure the health and safety of the residents in a long-term care facility.

*Comment*

The last sentence of this section requires an LMRO to receive approval from the Department before taking disease prevention and control measures. The Department should explain how this is to occur, and whether the requirement needs to be in writing.

*Response*

This section requires only a local health authority that is not an LMRO to obtain approval from the Department. This is intended to ensure that those local health authorities without experience in dealing with disease control measures have the benefit of the Department's expertise before taking action. The Department has changed the last sentence of the proposed regulation to use the term "LMRO" rather than "local health department" since that is consistent with the remainder of the Department's regulations on disease control. The Department will contact the local health authority by telephone, facsimile or in writing, depending upon the circumstances of the case and the urgency for action to be taken to control and prevent the spread of disease.

*Section 27.67. Movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department.*

This section requires certain actions to occur before persons or animals subject to quarantine or isolation by action of the Department or a local health authority can be moved from one place to another.

*Comment*

The Department should add the word "person" in front of the word "animal" in subsection (d).

*Response*

The Department agrees, and has revised the regulation.

*COMMUNICABLE DISEASES IN CHILDREN AND STAFF ATTENDING SCHOOLS AND CHILD CARE GROUP SETTINGS*

This part of Subchapter C includes criteria for exclusion and readmission of children and staff in schools and in child care group settings, and lists the diseases and symptoms for which exclusion may occur. It also includes a section that requires exclusion from child care group settings if a child does not have the listed immunizations or immunities. The Department received several comments on the sections in this part of the subchapter. Several comments were directed at the substance of this part of the subchapter, rather than to a particular regulation.

*Comment*

The heading of this part of the regulations uses terms like "children" and "staff" while the sections in this part use the term "pupils." The Department should review this part for consistency, and use terms consistently.

*Response*

The Department agrees with the comment. It has amended the proposed regulations to use the terms "child" and "children" rather than "pupil," and the phrase "staff having contact with children" rather than "staff."

*Comment*

A physician or school nurse should not have to verify that criteria for readmission have been satisfied unless

there is a question on the part of the school or child care group setting regarding whether the criteria have been satisfied. The criteria specified by the Department for readmission are very clear for most conditions, and to require a doctor or nurse to verify them would be a waste of time and resources. For example, physicians can do no more to ascertain the status of the child than a caregiver, who would ask the parents about whether the first crop of vesicles of chickenpox developed, and whether all the lesions have dried and crusted. Physicians and parents do not have to interact to confirm this status.

The times when a health professional needs to be included are clearly stated in the readmission criteria for conditions where the involvement is appropriate. When negative culture tests are required, the tests require involvement of a health professional as stipulated in the exclusion criteria.

*Response*

The Department has not changed the proposed regulations in response to this comment. The disease situations listed in this portion of the regulations that require verification for readmission to a school or group child care setting by a physician or a school nurse are situations that pose serious medical consequences to the individual with the disease, and to those exposed to the disease, if the individual remains communicable. Where the regulations require verification by physicians or school nurses for readmission, that verification is necessary to prevent and control the spread of disease.

*Comment*

Nonpublic schools do not have full-time school nurses. There are no school nurses functioning in many nonpublic schools. If no other type of personnel is assigned to perform this function, how can children be readmitted?

*Response*

The Department has not changed the proposed rulemaking in response to this comment. Whether a school is public or nonpublic does not change the risk to children exposed to a communicable disease. Further, although a school nurse may not be stationed daily at a nonpublic school, school nurses are available from the district. If one is not due for a visit at the time readmission criteria must be verified, the private school may request that one come to the private school for that purpose. The law requires that the school district make health services available to public and private school children. See 24 P. S. § 14-1402(a). School nurses are made available to nonpublic schools by the school district (id. at (a.1); and § 23.51 (relating to children to be provided school nursing services)). The number of school nurses to be provided within a school district is calculated based on the number of private and public school children within that district. See 24 P. S. § 14-1402(a.1). Therefore, by law, there must be access to school nurse services by children of private schools. Further, as the regulations state, in the absence of a school nurse, a physician's certificate is acceptable.

*Comments*

To require verification by a school nurse is a problem, because public schools do not have school nurses in every building every day. Further, the function of a school nurse is to focus on children, not the employees of the school.

Given the concern over lack of school nurses, why is verification of the criteria for readmission limited to a school nurse or a physician? Would verification from other medical personnel meet the requirements?

*Response*

The Department has not changed the proposed regulations in response to these comments. As is the case with private schools, if a school nurse is not present in a particular building, the school nurse may be sent for to verify readmission criteria. Again, a physician's verification need not be reverified by a school nurse. Lastly, Article XIV of the Public School Code of 1949 (24 P. S. §§ 14-1401—14-1422), which addresses school health services, includes requirements for the health of school staff. See 24 P. S. § 14-1418. If the staff in contact with children have a communicable disease of the type listed in the regulations, the health of the children with whom that staff are in contact could be compromised. To prevent and control the spread of disease within the school community, the health of all members of that community must be monitored. Infected staff can infect children.

*Comment*

The Department should reconcile the exclusionary language in this part of the regulations with the CDC's *Personnel Health Guidelines* which were published on September 8, 1997.

*Response*

The Department has not changed the proposed regulations in response to this comment. The guidelines to which the commentator refers are guidelines for hospital-based infection control. The Department's requirements are broader in this particular part of the regulations, in that they are directed toward prevention and control of the spread of disease in schools and child care group settings. The difference in setting requires a different approach. Individuals in a hospital setting are exposed to more virulent and different types of infections and are more likely to be in a fragile state susceptible to transmission of disease.

*Comment*

The Department should change the language of §§ 27.71—27.75 to read "children in child care and pupils in schools," and add the words "child care group settings" and "caregiver" to the sections. The reference to §§ 27.71—27.75 in § 27.76 (relating to exclusion and readmission of children, and staff having contact with children, in child care group settings) would then be unnecessary.

*Response*

The Department has not changed the proposed regulations in response to this comment. The Department is satisfied with the language in § 27.76 that expressly applies §§ 27.71—27.75 to child care group settings, with appropriate modifications.

*Comment*

The Department should make immunization delivery a reportable event, as the city of Philadelphia has done. This would allow future implementation of a Statewide immunization system, or registry. The language allowing for this should permit all health care providers or insurers to report, and should include immunity for violations of privacy and confidentiality of medical records.

*Response*

The Department is taking this comment into consideration. However, given the many serious issues surrounding the actual development and implementation of a registry process, more time is needed to consider the possibility of a registry, and how it would be implemented. For example, issues concerning whether persons

other than the Department would have access to the registry, how that access would occur, whether or not patient consent to be a part of the registry must be obtained, and how registration would occur, must be taken into account. More public comment should be invited than is possible at this stage in this rulemaking process. Further, the Department could not create immunity for providers and insurers from privacy and confidentiality laws, without having the statutory authority to do so. If the Department decides to pursue implementation of reporting of immunization delivery, the most appropriate way to do so is through separate rulemaking.

*Section 27.71. Exclusion of children, and staff having contact with children, for specified diseases, infections and conditions.*

This section requires exclusion of children, and staff persons who have contact with children, from school when a physician or school nurse suspects that individual of having any of the communicable diseases, infections or conditions listed in the section.

The Department has made a revision in paragraph (5), with respect to the exclusionary requirements for rubella. The proposed rulemaking had changed the number of days from the onset of rash from four to seven. The number should have remained four.

*Comment*

The Department should add Neisseria meningitidis to the list of diseases for which children and staff having contact with children are excluded. The exclusion should last until the person is made noninfective by a course of rifampin or other drug which is effective against the nasopharyngeal carriage state of this disease, or until otherwise shown to be noninfective. This requirement is included in child care group settings, but is missing from this regulation relating to schools.

*Response*

The Department agrees with this comment, and has added the disease to the regulation.

*Comment*

The Department should clearly define what adults are affected by these sections. What does contact with pupils mean? Does a staff person who has contact with pupils mean only teachers and administrators, or does it also include custodians, cafeteria workers and bus drivers? The Department should develop a definition of "school employee" that indicates who is to be excluded from the definition, and who included in it. The Department could define a "school employee" as an individual employed by a school. This definition would include an independent contractor or employee, and would exclude an individual with no direct or routine interaction with students.

*Response*

The Department's use of the phrase, "staff having contact with children," is meant to include all persons present in the school to perform duties for the school—volunteers, employees and independent contractors—who come into contact with children. To clarify this for the public, the Department has added language to the regulations referencing volunteers, along with a general definition of "volunteer" in § 27.1.

Further, the Department has intentionally used the phrase "having contact with children" and has not qualified the contact as routine or indirect. The regulations include every person performing duties for the school, paid or unpaid, who has any contact with children. Even a nonroutine or indirect contact of an infected person with a very young child, depending upon the circumstances of that contact, can and has caused severe illness in the child. If the school has knowledge of or a suspicion that the person has one of the diseases, infections or conditions included in the regulations, that person is to be excluded. This is necessary to prevent transmission of illness between staff, including volunteers, and the children. The illness in some cases, may result in death or serious disability.

*Comment*

It is not clear if volunteers are meant by the Department's use of the phrase "staff having contact with children," although the preamble to proposed rulemaking did say that they were. The regulations do not include the word "volunteer." Volunteers should not be included in these regulations, since these people are present at the school at different times throughout the school year. It would be difficult for school personnel to medically monitor these persons and comply with exclusion and readmission requirements that are more appropriately directed to students and to school employees. The Department should eliminate any requirement that volunteers be covered, but should include language that emphasizes the ability of the school staff to exclude these volunteers if a health risk is present.

*Response*

The Department has explained why volunteers are covered in prior responses to comments. The requirement under the regulations is, as the commentator has suggested, to exclude these persons if the school believes there is a health risk present. Once excluded, the individual cannot be readmitted unless the requirements of the regulation are followed.

*Comment*

Specific time frames for readmission are not mentioned under these diseases. If a specific time frame is satisfied, is it necessary to incur the expense of an additional doctor's visit? Wouldn't verification by a nurse or physician's assistant be satisfactory? This is more easily obtained and less expensive.

*Response*

The Department has not changed the proposed regulation in response to this comment. The text following most of the diseases listed in this section does include specific time frames for readmission running from a specific event in the course of the disease. The Department has provided a time frame for readmission for the remainder of the listed diseases predicated upon a specific event readily ascertainable which occurs in the course of the disease.

With respect to the comment asking whether verification of readmission criteria by a nurse or physician's assistant would be sufficient, the Department has already explained its reasons for requiring verification by a school nurse or physician in its response to general comments on this portion of the regulations relating to requirements for schools and child care group settings.

*Section 27.72. Exclusion of children, and staff having contact with children, for showing symptoms.*

This section requires exclusion of children and of staff having contact with children who are showing the symptoms listed.

*Comments*

The Department is to be commended for including language that is consistent with currently published National standards.

The Department should include diarrhea as a symptom permitting temporary exclusion of a pupil or staff person from a school or college to the extent the person may represent a communicable disease risk. The language would then be consistent with §§ 27.76(a)(3), 27.154(6) and 27.155(6) (relating to exclusion and readmission of children, and staff having contact with children, in child care group settings; restrictions on caregivers in a child care group setting; and restrictions on health care practitioners).

*Response*

The Department agrees with the latter comment and has added persistent diarrhea as a symptom for which exclusion is required.

*Comment*

A child who has a fever or is vomiting would have to be excluded under this section. This would require a child to be seen by a physician or school nurse whenever they have an upset stomach to be readmitted.

*Response*

The symptoms chosen by the Department to require exclusion were intended to be those that could be associated with a serious communicable illness of a child. For example, the Department requires exclusion of a child for a fever when the fever is equal to or greater than 102° F. The Department has changed the regulation to require exclusion for persistent vomiting rather than a single incident of vomiting for the reason raised by the commentator.

*Comments*

It is not practical to expect schools to keep abreast of what constitutes an unusual rate of absenteeism as published in the *Pennsylvania Bulletin*.

The term "periodically" in subsection (b), which states that the Department will periodically determine and publish what increase constitutes an unusual rate of absenteeism, is unclear. Will this be quarterly, annually or monthly? The Department should establish a time frame and say where the information will be published.

*Response*

The Department has deleted this statement from the regulation. A school may determine itself what constitutes an unusual rate of absenteeism, by a review of its records relating to absenteeism.

*Comment*

Subsection (b) requires schools to maintain records of exclusion of staff and students. This language is broad. Does a school have the authority to determine what an unusual rate of absenteeism is, and how often would it review its records to determine this rate? Development of guidelines and forms by the Department would be helpful to assist in these new recordkeeping duties. Will school districts be required to submit reports to the Department? The language implies this, but does not require it. The Department should clearly state that schools must submit the information, and specify the reporting process

*Response*

The regulation neither requires a school to submit records of exclusion or rates of absenteeism to the Department, nor specifies regular review periods for the records. The Department does not want this information reported on a regular basis. The Department expects that when a school notices something unusual occurring with respect to the number of children being excluded or absent, the school will review its records, and notify the Department through the disease reporting process. There are no special forms for this report.

As stated previously, the Department, through this chapter, intends to obtain the widest variety of information available on possible outbreaks of disease. One possible avenue for this information is through absenteeism rates at schools. If the school fails to notice something unusual, it is possible that the Department could locate the outbreak through other reporting sources. It is also possible, however, that information from a school could provide the Department with early warning of a problem in the community.

*Section 27.73. Readmission of excluded children, and staff having contact with children.*

This section sets standards for readmission into a school of children, and staff having contact with children, who were excluded under §§ 27.71 and 27.72.

*Comment*

The first part of subsection (a) should be deleted, since the exclusion criteria that require health professional decision making are already included in the criteria for the specific conditions and symptoms.

*Response*

The Department has not changed the proposed regulation based on this comment. The Department believes the language is necessary for the clarity of the section.

*Section 27.74. Readmission of exposed or isolated children, and staff having contact with children.*

*Section 27.75. Exclusion of children, and staff having contact with children, during a measles outbreak.*

The Department received no comments on §§ 27.74 and 27.75. The Department has, however, revised these sections consistent with revisions it has made to other sections in Subchapter C. The Department has added language to both of these sections to ensure that volunteers are covered by their provisions, and has clarified that the Department is concerned with all staff having contact with children, as it has in the other sections in this part of Subchapter C.

*Section 27.76. Exclusion and readmission of children, and staff having contact with children, in child care group settings.*

This section includes exclusion and readmission criteria for children and staff in child care group settings.

*Comment*

How will staff and management in a child care group setting be able to screen and diagnose children for exclusion? How will they be able to report at the same level as a health care facility?

*Response*

The regulations do not require management and staff to diagnose diseases, infections and conditions. If management or staff suspect that a child in the child care setting has one of the diseases, infections or conditions listed in the regulations for which a child or staff person must be excluded, or is showing signs and symptoms of that disease, infection or condition, or if the parent or guard-

ian makes the child care group setting aware that the child has a disease, infection or condition for which the child must be excluded, then the child should be excluded. The same reasoning should be applied to staff. Readmission is contingent upon verification from a physician that the criteria for readmission have been satisfied.

The Department has revised subsection (b)(3) to clarify that the child care group setting must ensure that the condition which required exclusion has been resolved before the child may be readmitted.

*Comment*

Diarrhea should be deleted from the list of conditions that require physician approval for readmission to the child care group setting. A physician will determine whether there has been resolution of the condition by asking the patient if the symptoms have subsided. A child care operator can do this as well as a physician. The requirement for readmission should be retained, but physician approval should not be required.

*Response*

The Department has changed the wording of subsection (a)(3) to require physician approval only if persistent diarrhea occurs. Since persistent diarrhea is most likely an indication of disease, unlike the incidence of sporadic diarrhea, the Department believes that a physician's approval is necessary to determine the nature of the disease and its resolution. Further, physician verification is required under this subsection when diarrhea is coupled with other symptoms or circumstances. Both together are evidence of serious illness, rather than a minor stomach condition.

*Comment*

The requirement in subsection (a)(3) that a person be excluded for diarrhea when associated with an identified bacterial or parasitic pathogen is too broad. Children and staff who are carriers of Giardia lamblia do not need to be excluded from child care. Similarly, asymptomatic children with salmonella other than s. typhi in their stools do not need to be excluded.

*Response*

The Department has not changed the proposed regulation in response to this comment. The presence of a bacterial or parasitic pathogen is only cause for exclusion under subsection (a) when it is coupled with persistent diarrhea. (The Department has changed the term "diarrhea" to "persistent diarrhea" to evidence a serious illness, as has been discussed.) Therefore, asymptomatic children would not be excluded under this provision; the only children who would be excluded would be children who had a persistent symptom. The persistent symptom, diarrhea, particularly when it occurs among very young children, can easily transfer infection by hand-to-mouth contact.

*Comment*

Subsection (a)(8) should say "influenzae" rather than "influenza." However, there is no reason to exclude children or staff members from a child care group setting for H. influenzae disease.

*Response*

The Department agrees, and has deleted the text of proposed subsection (a)(8). Cases are no longer infectious 24 hours after antimicrobial treatment begins. At that time, the child would pose no threat of infection to other children. Prior to treatment, the child will be obviously ill, and will either be kept home by parents or guardians, or will fall under another exclusionary provision of the regulations.

*Comments*

Subsection (b)(3) requires a caregiver to screen every child for the presence of a condition that requires exclusion. This would require the caregiver, or a school perhaps, to screen for all diseases listed as well as symptoms. This is unreasonable, burdensome, costly and time consuming. This would require a child to be subjected to a daily medical examination. How would this be administered?

Does this mean a caregiver would have to screen a child every day for the presence of an exclusionary disease, or only if the child is suspected of having a disease?

The Department should clarify whether the caregiver is required to make an accurate diagnosis of the child's condition, or is to screen for symptoms of the child's condition.

*Response*

This subsection does not apply to schools. This subsection applies when children are returned to a child care group setting following an exclusion under the regulations. The Department realizes that the proposed paragraph reads otherwise, and has revised it so that it clearly applies only when a child is returned to a group care setting following an exclusion.

*Comment*

How will the caregiver report the presence of an exclusionary disease to the Department? Is there a form required by the Department? The Department must fully explain how to report.

*Response*

This section deals with exclusion and readmission of children and staff having contact with children in a child care group setting. Child care group settings are required to report diseases, infections and conditions under § 27.23. Reporting is done in accordance with § 27.4. The time frames in which reports must occur are included in § 27.21a. Further discussion concerning case reporting is included in the Department's responses to comments on § 27.4.

A person who has a question concerning the appropriate reporting requirements may call the Department's district office or the local health department in the area in which the person is located.

*Section 27.77. Immunization requirements for children in child care group settings.*

This section requires children in child care group settings to have certain immunizations, and sets standards for excluding those children from the setting for failure to obtain those immunizations.

*Comment*

The DPW governs the development, implementation and enforcement of regulations in this area. Operators of child care group settings will take the information provided by the Department relating to disease control and prevention in an effort to improve quality of care. The Department's regulations, however, conflict with standards being followed by home-based providers in the area of procedures involving matters such as communicable diseases.

*Response*

The Department has not changed the proposed regulation in response to this comment. Although the DPW may be the licensing agency for child care homes, the Department is the agency with the authority, delegated by the General Assembly, to prevent and control the spread of disease throughout this Commonwealth. The Department has the broad authority to take the necessary steps to prevent and control the spread of disease. The Department has worked and will continue to work with DPW to ensure that entities licensed by that agency are aware of reporting requirements.

*Comment*

There is no separate definition for schools or child care providers, rather, there is a single definition for child care group setting. Since the exemption provision in subsection (d) references schools, this implies that a child care group setting includes a school, unless specific exemptions are included in the language.

*Response*

Section 27.77 does not apply to schools. This is made clear under subsection (d). Regulations relating to exclusion of children from schools for failure to obtain immunizations already exist. See § 23.85 (relating to responsibilities of schools and school administrators) and 22 Pa. Code §§ 11.20 and 51.13 (relating to nonimmunized children; and immunization). There is no need to promulgate regulations twice on the same topic.

*Comment*

The documentation of vaccination status under subsection (a) would impose a heavy administrative burden on the child care group setting, and would require a level of expertise that cannot be met with the resources currently available to child care group settings. These settings do not have health professionals available to help with immunization record checks.

*Response*

The Department has not changed the proposed regulation in response to this comment. The Department must monitor to ensure that child care group settings are complying with the regulations, so that children within those settings are adequately protected from disease. The burden should be small on many child care group settings, since group child day care facilities licensed by DPW already are required to do health screening under DPW regulations, and report to DPW concerning vaccination status. See 55 Pa. Code §§ 3280.1—3280.221. These regulations require that a facility licensed by DPW conduct a health assessment of each child according to guidelines set by the American Academy of Pediatrics (AAP), and that a report be written that includes, among other things, a review of the child's immunization status according to AAP standards. See 55 Pa. Code § 3280.131(b), (c) and (d)(5). Therefore, child care group settings should have little difficulty in complying with the Department's regulations requiring documentation of a child's vaccination status.

*Comment*

The Department should consider using our software product to gather and track immunization information to other child care group settings not now under surveillance, as DPW does for its purposes.

Contrary to the Department's assessment in the preamble to proposed rulemaking of additional resources needed to implement the regulations, it will require additional resources to run immunization reviews in child care settings. The commentator is moving with DPW to require the full set of DPW's required forms from facilities. DPW has been working on this for years. Interfering with this careful groundwork and already operational system would be wasteful and regressive.

The commentator recommends that the Department and DPW work together collaboratively to develop, support and internalize existing systems of medical record checking that includes all recommended preventive health services (vaccinations and screening tests) as is now done by the commentator's software package.

Further, the child care facilities that must report under these regulations do not have resources available to perform these recording and reporting functions. Implementing the regulations will require the use of software that can apply complex decision rules about when vaccine should be received at varying ages, and that can track this information. The commentator has developed tools to help accomplish this.

*Response*

The Department declines to discuss the appropriateness of a particular software product in the context of its regulations. Any comment made by the Department could be viewed as circumventing the established bidding process for products and services, if one is instituted. The Department is currently incorporating a Statewide immunization information system into public clinic sites, and the information gathered through this regulation will be part of that system. This system will enable certain approved health care providers to easily access a child's immunization history, hopefully preventing unnecessary vaccinations, and facilitating the updating of a child's immunizations. For the present time, however, this immunization record will continue to be a paper record.

*Comment*

Subsection (a)(4) requires the caregiver to update certificates of immunization periodically. The term "periodically" is unclear. The Department should include a time frame.

*Response*

The Department is requiring certificates of immunization to be updated when new information regarding immunization is obtained. The Department has revised subsection (a)(4) to reflect this provision.

*Comment*

The Advisory Committee on Immunization Practices (ACIP) standards cited by the Department were superseded on January 1, 1999. New recommendations are made each January. The existing the DPW section references the existing standard, and therefore requires no revision.

*Response*

The Department has not changed the proposed regulation in response to this comment. The Department has accepted the standards in place on January 1, 1999, not the recommendations for immunization based upon those standards. Subsection (b)(2) states that the Department will deem an ACIP recommendation pertaining to the immunization of children to satisfy the standards of the subsection unless ACIP eliminates a standard and the recommendation is issued under the altered standards. This means that if ACIP recommends a new immunization in January of 2002, as long as that immunization

meets the standards set in subsection (b)(1), children in child care group settings are required to have that immunization.

*Subchapter D. SEXUALLY TRANSMITTED DISEASES, TUBERCULOSIS AND OTHER COMMUNICABLE DISEASES.*

*Section 27.84. Examination for a sexually transmitted disease of persons detained by police authorities.*

This section tracks section 8(a) of the act (35 P. S. § 521.8(a)) and sets standards for requiring persons detained by police authorities to be tested for sexually transmitted diseases.

*Comment*

Subsections (a) and (b) state that if a person refuses to undergo an examination or submit a specimen, the Department or a local health authority may take judicial action to secure an appropriate remedy. What does the phrase "appropriate remedy" mean?

*Response*

The phrase, when taken in conjunction with the previous phrase, means that the Department or a local health authority may ask a court of competent jurisdiction for a variety of relief. It may petition, as provided for in sections 7 and 11 of the act (35 P. S. §§ 521.7 and 521.11), for an order requiring examination, and, if necessary, treatment. It may prosecute the individual under section 20 of the act (35 P. S. § 521.20). It may petition the court for any appropriate remedy to allow it to enforce the requirements of the act, which require an individual taken into custody and charged with a crime involving lewd conduct or a sex offense, or any person to whom the jurisdiction of a juvenile court attaches, to be examined for a sexually transmitted disease. See 35 P. S. § 521.8. The Department will determine the appropriate remedy to pursue, if any, depending upon the case. Since the matter would be before a court, the individual against whom the petition is filed would have the opportunity to challenge the Department's requested relief. The relief granted will ultimately be up to the court.

*Section 27.87. Refusal to submit to treatment for communicable diseases.*

This section sets out the actions the Department may take if a person refuses to submit to treatment for a communicable disease. It is based on section 11 of the act.

*Comment*

The Department should revise the second sentence of subsection (b), as it is long and complex.

*Response*

The second sentence of subsection (b) reads as follows: "Upon the filing of a petition, the court shall, within 24 hours after service of a copy upon the respondent, hold a hearing without a jury to ascertain whether the person named in the petition has refused to submit to treatment." The Department believes that this sentence is clear as it is written.

*Comment*

Subsection (b) states that the Department or a local health authority may file a petition in the court of common pleas of the county in which the person resides asking the court to commit the person to "an appropriate institution." What is "an appropriate institution?"

*Response*

The type of institution appropriate for quarantining an individual will depend upon the person, the type of disease in question, and the availability of places to which the person may be committed. For example, for one case of multidrug resistant tuberculosis, when the individual involved was known to have drug and alcohol problems, the Department recommended to the court that the individual be sent to a drug and alcohol abuse treatment facility. The Department could recommend that the individual be placed in a hospital, or the individual's home, or some other type of institution, depending upon the circumstances and the available resources. The Department, or a local health authority, may recommend a type of institution for commitment, however, the court must approve that placement. The individual does have the opportunity before that court to object to the Department's or local health authority's recommendation. A copy of the petition must be served on the individual who is the subject of the petition. See 35 P. S. § 521.11(a.2).

*Section 27.89. Examinations for syphilis.*

This section includes standards for examinations for syphilis. Subsection (a) requires testing in the third trimester of pregnancy when the woman resides in a county where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions. Subsections (b) and (c) require testing of a woman who has had a live or stillbirth under the same circumstances.

The Department has added language to subsection (a)(1) to clarify that it is the person attending the pregnant woman who is to explain the importance of the syphilis test, and not the laboratory technician seeking to draw her blood.

*Comment*

In subsections (a)—(c), the Department has stated that it will publish in the *Pennsylvania Bulletin*, as necessary, the rate of syphilis at which the CDC determines it is cost-effective to require special precautions. What is the purpose of publishing the rate of syphilis? What criteria will be used to determine when it is necessary to publish the rate of syphilis?

*Response*

The purpose of publishing this rate in the *Pennsylvania Bulletin* is to alert health care providers that a syphilis test is required to be done in their county based on the rates at which the CDC has determined that it is cost-effective to require special precautions. To make it easier for physicians, the Department has stated in the section that, rather than publishing the rate determined by the CDC, the Department will publish a list of the counties in which that rate occurs. Reporting is only required in those counties where the annual rate of infectious syphilis is equal to or greater than the rate determined by the CDC.

At the present time, only Philadelphia has a rate of syphilis above the CDC-established rate. Therefore, these specific requirements will only apply to Philadelphia at the present time. This standard enables the Department to broaden surveillance to prevent congenital syphilis in the event the established CDC rate is exceeded elsewhere.

*Section 27.96. Diagnostic tests for sexually transmitted diseases.*

This section sets standards for tests used to determine the presence of a sexually transmitted disease.

*Comment*

This section should be deleted, since a separate section for standards is not required. Diagnostic tests for all diseases should be done following standard or approved test procedure, including using Food and Drug Administration approved tests when applicable.

*Response*

The Department has not changed the proposed regulation in response to this comment. The act requires that the standard or approved test procedures for each of the sexually transmitted diseases be a test approved by the Department, and that if a laboratory test is part of the approved procedure, it should be done in a laboratory approved by the Department to make the tests. See 35 P. S. § 531.12.

*Section 27.97. Treatment of minors.*

This section includes language from section 14.1 of the act (35 P. S. § 521.14a) and section 3 of the act of February 13, 1970 (P. L. 19, No. 10) (35 P. S. § 10103), both of which provide for a minor to give effective consent for certain medical and health services without the consent of any other person. Section 14.1 of the act and section 5 of the act of February 13, 1970 (35 P. S. § 10105) also state that a physician who provides treatment under the given circumstances is not liable for properly administering appropriate treatment to the minor.

*Comment*

The Department should add language to this section defining health services to include venipuncture and clinical laboratory testing. The section should also state that a laboratory may not be sued or held liable for venipuncture or testing services if the minor consents.

*Response*

The Department has not changed the proposed regulation in response to this comment. Under statute, a minor can give consent for "medical and health services to determine the presence of or to treat pregnancy, and venereal disease and other diseases reportable under the [act] . . . ." (35 P. S. § 10103). Since neither the Department nor local health authorities enforce this statutory provision, it is up to the individual health care provider to determine whether the phrase, "to determine the presence of" would include venipuncture and laboratory testing, so that consent of a minor would be sufficient. The Department cannot provide clinical laboratories with immunity through regulation. Only the General Assembly can grant immunity, which it has done in this case to physicians who act appropriately under the statute, and provide appropriate treatment. See 35 P. S. §§ 521.14a and 10105. The legislature has not seen fit to extend that immunity to clinical laboratories.

*Comment*

This section raises serious concerns. The regulations the Department is amending allow for consent for treatment for venereal disease, however, these regulations broaden it to all communicable diseases. A minor could give consent to a cancer workup without parental consent. The Department must be cognizant of parental rights. There should be further legal review of this section.

*Response*

Further legal review is unnecessary. The General Assembly has already directed through the act of February 13, 1970 (P. L. 19, No. 10) (35 P. S. §§ 10101—10105) that a minor may consent to medical and health services for pregnancy, sexually transmitted diseases, and other diseases reportable under section 3 of the act of February 13, 1970, or when an attempt to secure consent would result in delay of treatment which would increase the risk to the minor's health under section 4 of the act of February 13, 1970 (35 P. S. § 10104). The regulation tracks these statutes. The Department has not changed the proposed rulemaking.

*Section 27.98. Prophylactic treatment of newborns.*

This section requires the application of certain medications to the eyes of a newborn child, unless the parent or guardian objects for religious reasons.

*Comment*

The Department should add "or if in the opinion of the attending physician treatment is not advisable," before the phrase "prophylactic treatment shall be withheld."

*Response*

The Department agrees with the comment. The addition of the language is necessary to take into account the health and safety of the newborn. The Department has added the language to the regulation.

*Section 27.99. Prenatal examination for hepatitis B.*

Subsection (a) requires a pregnant woman to undergo immunologic testing for the presence of hepatitis B antibodies, but permits her to object to the testing on religious grounds. Subsection (b) requires that, if the mother tests positive for hepatitis B surface antigens, the baby receive prophylactic treatment, and again provides a religious exemption.

*Comment*

The Department should delete the religious exemption from subsection (b). No parent has ever expressed a religious objection to treating the infant for exposure to its mother's hepatitis B to prevent chronic disease in the infant. It seems unlikely that this could be challenged in court.

*Response*

The Department has not changed the proposed regulation in response to this comment. The fact that the commentator is not aware of the challenge of any parent or guardian to this treatment of the newborn does not mean that a parent or guardian does not have the right to reject medical care for the child. The Department must take that right into account in writing its regulations, and cannot mandate the treatment of the infant in this instance. The regulation does not prevent the hospital or attending physician from challenging the objection of the parent or guardian in a court of law, if they feel it is necessary to do so.

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

*Section 27.151. Restrictions on the donation of blood, blood products, tissue, sperm and ova.*

This section sets standards for the donation of certain materials from the human body.

*Comment*

In subsection (a), the Department should add the words "or suspected" to the phrase "a person known to be infected with the causative agent of a reportable disease . . . ."

*Response*

The Department agrees with this recommendation, and has added the words "or suspected of being" to the regulation.

*Comment*

In subsection (b), the Department should add "from a person known or suspected of being infected with the causative agent of a reportable disease" before "for donation" and "and" before "without obtaining." If the donor who has the infection is prohibited from donating, the receiving agency should also be prohibited from accepting the donation. Screening tests will prevent donations from persons with HIV, hepatitis B and C, but from none of the other diseases.

*Response*

The Department agrees with the comment, and has added the recommended language "from a person known or suspected of being infected with the causative agent of a reportable disease."

*Section 27.152. Investigation of cases and outbreaks.*

This section states that the Department or a local health authority may investigate any case or outbreak that either believes is a potential threat to the public health. It also requires cooperation with the investigator from health care practitioners, facilities, other institutions and the public, provided that the representative presents documentation establishing that he is an authorized representative.

*Comment*

What type of documentation is required to establish that the person is an authorized representative of the Department or a local health authority? Is a name tag sufficient to meet this requirement?

*Response*

An official form of Department or local health authority identification would be sufficient. Department staff have photo identification cards, but do not wear name tags. A letter bearing official signatures would also be sufficient. For example, Department staff will often carry a letter from the Secretary of Health on Department stationary when attempting to require compliance with a drug treatment regimen for tuberculosis. Any method which clearly establishes that the person performing the investigation is a representative of the Department or a local health authority is acceptable.

*Section 27.153. Restrictions on food handlers.*

This section limits the ability of persons with the listed diseases or conditions to work as food handlers.

*Comment*

The Department should reconcile the requirements of this section and of § 27.154 (relating to restriction on caregivers in a childcare group setting) with the CDC's *Personnel Health Guidelines* that specifically deal with the prevention of nonsocomial transmissions of selected infections. In particular, the Department should reconcile the differences with respect to hepatitis A and diarrhea.

*Response*

The Department has not changed the proposed regulations to address this comment. The guidelines referred to by the commentator were crafted for hospital settings and are concerned with nosocomial transmissions of disease. The Department sees no conflict between its regulations, drafted to meet more general public health requirements, and those guidelines. The Department is available to provide guidance on these issues as is necessary.

*Comment*

The use of the term "diarrhea" in this section and § 27.154 is outdated. That term should be replaced with the term "gastroenteritis."

*Response*

The Department has not changed the proposed regulation in response to this comment. The term "diarrhea" most accurately describes the symptom with which the Department is concerned. The term "gastroenteritis" is a general description of a variety of illnesses, and does not convey the need for a demonstrative symptom which may be measured.

*Comment*

The Department should add "or paratyphi" after "typhi" in paragraph (4). The same revision should be made to § 27.154 and § 27.155 (relating restrictions on health care practitioners).

*Response*

The Department agrees that paratyphi should be added to paragraph (4) of each of these three sections. The Department has revised all three sections accordingly.

*Section 27.154. Restrictions on caregivers in a child care group setting.*

This section limits the ability of persons with the listed diseases or conditions to work as caregivers in a child care group setting.

*Comment*

Diarrhea should be deleted from the list of conditions that require physician approval for readmission to the child care group setting. A physician will determine whether there has been resolution of the condition by asking the patient if the symptoms have subsided. A child care operator can do this as well as a physician. The requirement for readmission should be retained, but physician approval should not be required.

*Response*

The Department has not changed the proposed regulation to address this comment. The Department has addressed the comment in its response to a similar comment on § 27.76.

*Section 27.155. Restrictions on health care practitioners.*

This section limits the ability of persons with the listed diseases or conditions to work as health care practitioners.

*Comment*

The Department should provide education sessions regarding disease reporting across this Commonwealth. There are differences in how various local health authorities and other health departments work with health care practitioners and health care facilities in disease reporting, the presence or absence of a county health department dictates the way diseases are reported, and special requirements for certain diseases exist. It would be beneficial for the Department to discuss its plans regarding electronic reporting, to review the forms required, and to provide contacts and telephone numbers for each county as appropriate.

*Response*

The Department agrees that education regarding disease reporting would be beneficial, to reacquaint practi-

tioners and facilities with disease reporting requirements. The Department will provide a list of LMROs, which will include the county/municipal health departments, upon request. A more detailed discussion of the Department's plans regarding electronic reporting is included in its response to the general comments on these regulations.

*Comment*

The Department should include a hospital-based infection control practitioner on the Department's task forces or on the Board to ensure that the perspective of health care facilities are considered and addressed.

*Response*

The members of the Board are appointed by the Governor, and, by statute, must fall within certain specified categories. The Board is to be comprised of 13 members, including the Secretary of Health, five of whom must be physicians, one a dentist, one a pharmacist, one a registered nurse and one an engineer. See section 448 of The Administrative Code of 1929 (71 P. S. § 158). The Department agrees that an individual with experience in facility-based infection control could be an asset to the Board, and will consider recommending such an individual to the Governor for appointment once an appropriate vacancy occurs.

The Department does, however, have doctorate level staff, including physicians, with expertise in infectious disease control. These persons do discuss issues with hospitals and their infectious disease staff.

*Comment*

Is there a more comprehensive way to describe a potentially infectious case of diarrhea versus a 1 day condition due to a known strain of influenza than the language in paragraph (6)? Paragraph (6) also suggests that an evaluation by a physician is necessary for readmission to work as a health care practitioner. The Department may wish to consider defining the term "resolved."

*Response*

The Department's intent was to address only potentially infectious diarrhea in this section, and in §§ 27.153 and 27.154. Therefore, the Department has changed the listed condition to "persistent diarrhea" to clarify this intent.

*Section 27.158. Special requirements for shigellosis.*

This section prohibits household contacts of persons with shigellosis who have certain employment that could expose others to the disease from performing that work until the requirements of the section are met.

*Comment*

The Department should define the term "household contact" or provide examples.

*Response*

The Department has added a definition of "household contact" to the definition section of the regulations. The term is intended to apply to any person living in the same residence as a case, whether or not the individual is related.

*Section 27.161. Special requirements for tuberculosis.*

This section includes standards for the isolation of persons with tuberculosis, and requirements for testing close human contacts of that person.

*Comment*

Subsection (b) defines a close human contact as a person who spends a substantial amount of time with the person who has infectious tuberculosis. The term "substantial" should be deleted, and a specific time frame included.

*Response*

There are no definite guidelines published by the CDC on time frames for determining who is a "close contact." Further, what constitutes "substantial" could differ depending upon who the other individuals are and the circumstances surrounding the case. For example, a young child is more susceptible to contracting tuberculosis than an older person, and less time in contact with the infected individual could be necessary for a child to contract the disease. Therefore, it would be impossible to specify a definite time frame in the regulations. "Substantial," as used in this section, means anything more than casual contact. However, the Department must be able to determine who are close human contacts and who are casual contacts on a case-by-case basis, based on the characteristics of the individuals and the circumstances surrounding the contact.

*Subchapter F. MISCELLANEOUS PROVISIONS*

*Section 27.183. Occurrence of psittacosis.*

This section requires certain disease prevention and control measures to occur when a case of psittacosis is found in humans or in birds.

*Comment*

The Department should add a subsection (c) that states:

> "A bird with psittacosis that has been placed under quarantine may not be sold or removed from its isolation quarters until it has been treated for at least 7 days. After 7 days, it may be sold, but the buyer must be made aware in writing with a signed receipt of the significance of psittacosis and the signs and symptoms for which to look. The signed receipt paperwork will include a copy of any documents provided to the new owner, and will be maintained at the place of sale for 6 months after the sale of the quarantined bird. The duration of additional treatment necessary must be established at the time of sale, and a supply of medicated feed sufficient for the duration of the treatment must be provided to the new owner."

*Response*

The Department agrees with this recommendation, and has added the language. This requirement is a National practice standard relating to psittacosis, and has been added to the CDC's compendium on psittacosis.

*Section 27.201. Disposition of articles exposed to contamination.*

This section includes requirements for the disposition of bedding, clothing or other articles that have been exposed to contamination from specific communicable diseases.

*Comments*

The Department should explain why it has deleted certain diseases and added others to this section.

The Department should retain references to smallpox (variola, varioloid) in this section, since there is the possibility of a bioterrorist attack using this infectious agent.

*Response*

The Department agrees with the latter comment, and has reinstated references to smallpox (variola, varioloid) into this section. Because the Department is not deleting any diseases from the section, no further response to the first comment is necessary.

*Comment*

The Department should explain or reference what a proper precaution to be taken is when there is a transmission of articles that have been contaminated.

*Response*

Appropriate precautions to be taken to decontaminate articles exposed to smallpox, plague or anthrax so that they may be safely transmitted from one person to another depend upon the circumstances of the case, including the type of disease involved and the manner in which it is spread. The Department and local health authorities do not expect individuals to determine what these appropriate precautions are. The Department will make recommendations concerning what type of precautions are necessary on a case by case basis.

*Section 27.202. Lease of premises occupied by a person with a communicable disease.*

This section includes requirements for renting out a room, house or part of a house in which a person with a communicable disease has been.

*Comment*

The Department has deleted from this section language that requires these places to be cleaned to the Department's satisfaction. What is the standard of cleanliness that must now be met?

*Response*

The Department agrees that the original standard provided more guidance than the proposed regulation, and has retained the language it had proposed to delete from this section.

*Section 27.203. Preparation for burial or transportation of deceased human bodies.*

This section requires persons handling deceased human bodies to take appropriate precautions to prevent the spread of communicable diseases.

*Comment*

The statement that appropriate precautions should be taken is vague. The Department should give examples of appropriate precautions in the final form regulations.

*Response*

The Department agrees that there is a need for more explicit standards in this section, and has retained the language it had proposed to delete.

*CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES*

*Section 211.1. Reportable diseases.*

This section lists communicable diseases that long-term care nursing facilities are required to report. The Department is amending this section as has been previously discussed in commentary on § 27.21a.

C. *Affected Persons*

The amendments impact on health care providers, health care practitioners, clinical laboratories, health care facilities and child care group settings in this Commonwealth. The amendments also impact on local health authorities, including the ten county/municipal health departments. These entities shall comply with the updated disease reporting procedures, which are not, however, significantly different from current reporting requirements.

Additionally, every citizen in this Commonwealth is affected by the amendments as each will benefit from a reduced risk of exposure to, and resulting morbidity and mortality from, infection with the more than 50 reportable diseases, infections and conditions.

All reporters will be affected by the Department's phasing in of an electronic reporting system. Reporting electronically will make reporting easier and more efficient, and, since reporting software and training will be provided at no cost to the Department, will not increase reporting costs for providers.

D. *Cost and Paperwork Estimate*

The amendments will have no measurable fiscal impact on the Commonwealth, local government, the private sector or the general public because the disease reporting system already exists in this Commonwealth. In fact, the application of Nationally accepted state-of-the art public health practices and communicable disease prevention and control strategies within this Commonwealth should create savings in related health care costs each year. The regulated community and local governments will see a benefit directly proportional to the numbers and types of disease cases prevented, thereby reducing community health care costs. This Commonwealth will also benefit in an amount directly proportional to the numbers and types of disease cases and disease outbreaks prevented, thereby greatly reducing State government health care costs.

The amendments fine-tune an already existing disease reporting system in this Commonwealth and will not result in additional paperwork. Newly listed reportable diseases, infections and conditions will be reported and investigated in a manner similar to the reporting and investigation of currently listed diseases, infections and conditions, using National case-definitions and investigation forms provided by the CDC.

E. *Statutory Authority*

The Department's overarching authority to promulgate these regulations is found in the act. Section 16(a) of the act gives the Board the authority to issue rules and regulations on a variety of matters relating to communicable and noncommunicable diseases, including the following: the diseases that are to be reported; the methods of reporting diseases; the contents of reports; the health authorities to whom diseases are to be reported; the control measures that are to be taken with respect to different diseases; the enforcement of control measures; the immunization and vaccination of persons and animals; the prevention and control of disease in public and private schools; the treatment of sexually transmitted diseases, including patient counseling; and any other matters the Board may deem advisable to address for the prevention and control of disease and for carrying out the provisions and purposes of the act. Section 16(b) of the act gives the Secretary of Health the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

There is also legislative authority for specific provisions of the regulations in other statutes. First, section 2102(g) of The Administrative Code of 1929 (code) (71 P. S. § 532(g)) provides general authority for the Department to promulgate its regulations.

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. Section 2106(b) of the code (71 P. S. § 536(b)) provides the Department with the authority to establish and enforce quarantines to prevent the spread of disease, and section 2106(c) of the code gives the Department the authority to administer and enforce the laws of the Commonwealth with respect to vaccination and other means of preventing the spread of communicable disease.

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 this Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

Section 2111(c.1) of the code also provides the Board with the authority to make and revise a list of communicable diseases against which children are required to be immunized as a condition of attendance at any public, private or parochial school, including kindergarten. The section requires the Secretary to promulgate the list, along with any rules and regulations necessary to ensure the immunizations are timely, effective, and properly verified. The regulations that primarily carry out this responsibility are in Chapter 23, Subchapter C (relating to immunization).

Other statutes speak to the Department's authority to promulgate regulations in relation to specific diseases, infections or conditions. The Newborn Child Testing Act (35 P. S. §§ 621—625) provides the Department with the authority to promulgate regulations listing reportable diseases and conditions in the newborn child, and setting out the operation of a program of screening, follow-up, assessment and diagnosis of newborn children for those reportable diseases and conditions. See 35 P. S. §§ 623 and 625. The Pennsylvania Cancer Control, Prevention, and Research Act (35 P. S. §§ 5631—5637) authorizes the Department to create a cancer registry to which persons in charge of hospitals and laboratories shall report cases of cancer in accordance with rules and regulations adopted by the Department with the advice of the Pennsylvania Cancer Control, Prevention and Research Advisory Board. See 35 P. S. § 5636(b). This legislation has been impacted by Federal legislation which was enacted in 1992, and which requires complete reporting of cancer cases to be made by all health care practitioners, and all hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer. See 42 U.S.C.A. §§ 280e and 280e-1—280e-4. The act of March 3, 1972 (P. L. 102, No. 37) (35 P. S. §§ 1071—1077), known as the Turtle Law, provides the Department with the authority to prohibit a person from bringing, causing to be brought or transporting any live turtle into this Commonwealth, unless the turtle or lot of turtles is accompanied by a permit issued by the Department or another agency authorized by the Department to issue a permit. The permit may only be issued if there is adequate biological proof that the turtles are free from salmonella. The same permit is required when the turtles originate within this Commonwealth.

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—922 and 1001—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.

The Public School Code of 1949 (24 P. S. §§ 1-101—26-2606-B), provides the Department with additional authority for disease prevention and control actions taken within schools. Section 1421(c)(2) of the Public School Code of 1949 (24 P. S. § 14-1421(c)(2)), provides the Secretary of Health, in consultation with the Secretary of Education, with the authority to promulgate regulations implementing the school health program. The requirements of the school health program are set out in Article XIV of the Public School Code, and provide, among other things, that pupils are released from compulsory attendance when they are prevented from attending by the health laws of the Commonwealth (24 P. S. § 14-1417), and that no persons having any form of tuberculosis in a transmissible stage may be a pupil, teacher, janitor or any other employee in a school, unless it is a special school. See 24 P. S. § 14-1418. Section 1303a of the Public School Code (24 P. S. § 13-1303a) provides that the Board will make and review a list of diseases against which children must be immunized, as the Secretary may direct, before being admitted to school for the first time. The section provides that the school directors, superintendents, principals or other persons in charge of any public, private, parochial or other school including kindergarten, shall ascertain whether the immunization has occurred, and certificates of immunization will be issued in accordance with rules and regulations promulgated by the Secretary with the sanction and advice of the Board. Most of the regulations carrying out these responsibilities are set forth in Chapter 23.

F. *Effectiveness/Sunset Dates*

These final-form regulations will become effective upon final publication in the *Pennsylvania Bulletin*. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 8, 1999, the Department submitted a copy of notice of proposed rulemaking published at 30 Pa.B. 2715 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 Regulatory Review 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 Regulatory Review Act (71 P. S. § 745.5a), the Department submitted a copy of the final-form regulations to IRRC and the Committees on November 26, 2001. 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 these final-form regulations, the Department has considered the comments received from IRRC, the Committees and the public.

These final-form regulations were deemed approved by the House Health and Human Services Committee and the Senate Public Health and Human Services Committee on December 17, 2001. IRRC met on December 20, 2001, and approved the regulations in accordance with section 5.1(e) of the Regulatory Review Act. The Attorney General approved the regulations on January 9, 2002.

H. *Contact Person*

Questions regarding these regulations may be submitted to: James T. Rankin, Jr., D.V.M., M.P.H., Ph.D., Director, Division of Communicable Disease Epidemiology, Department of Health, P. O. Box 90, Harrisburg, PA 17108, (717) 787-3350. 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 Dr. Rankin at the address or telephone numbers listed in this preamble so that necessary arrangements may be made.

I. *Findings*

The Department and the Board find 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 final-form regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes.

J. *Order*

The Department and the Board, acting under the authorizing statutes, order that:

(a) The regulations of the Department, 28 Pa. Code Chapter 27, are amended by adding §§ 27.5a, 27.6—27.8, 27.21a, 27.24a, 27.33—27.35, 27.41a, 27.42a, 27.43a, 27.60, 27.76, 27.77, 27.99 and 27.151—27.164; by amending §§ 27.1—27.4, 27.21—27.23, 27.29—27.31, 27.61, 27.65—27.69, 27.71—27.75, 27.81—27.85, 27.87—27.89, 27.95—27.98, 27.181, 27.183, 27.191, 27.192, 27.201, 27.202, 27.204 and 211.1; and by deleting §§ 27.5, 27.24—27.28, 27.32, 27.41—27.47, 27.51, 27.62—27.64, 27.86, 27.90—27.94, 27.101—27.146, 27.184 and 27.205 to read as set forth in Annex A.

(b) The Secretary of Health 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 of Health 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 of Health 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*.

ROBERT S. ZIMMERMAN, Jr.,
*Secretary*

**Fiscal Note:** Fiscal Note 10-156 remains valid for the final adoption of the subject regulations.

(*Editor's Note*: For the text of a notice pertaining to this rulemaking, see 32 Pa.B. 539 (January 26, 2001).)

**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:

*ACIP*—The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, United States Department of Health and Human Services.

* * * * *

*Caregiver*—The entity or individual responsible for the safe and healthful care or education of a child in a child care group setting.

* * * * *

*Case*—A person or animal that is determined to have or suspected of having a disease, infection or condition.

*Case report form*—The form designated by the Department for reporting a case or a carrier.

*Central office*—Department headquarters located in Harrisburg.

*Child*—A person under 18 years of age.

*Child care group setting*—The premises in which care is provided at any one time to four or more children, unrelated to the operator.

*Clinical laboratory*—A laboratory for which a permit has been issued to operate as a clinical laboratory under the Clinical Laboratory Act (35 P. S. §§ 2151—2165).

*Communicable disease*—An illness which is capable of being spread to a susceptible host through the direct or indirect transmission of an infectious agent or its toxic product by an infected person, animal or arthropod, or through the inanimate environment.

*Communicable period*—The time during which an etiologic agent may be transferred directly or indirectly from an infected person to another person, or from an infected animal to a person.

*Contact*—A person or animal known to have had an association with an infected person or animal which presented an opportunity for acquiring the infection.

* * * * *

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

*Health care facility*—

(i) A chronic disease, or other type of hospital, a home health care agency, a hospice, a long-term care nursing facility, a cancer treatment center using radiation therapy

on an ambulatory basis, an ambulatory surgical facility, a birth center, and an inpatient drug and alcohol treatment facility, regardless of whether the health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government.

(ii) The term does not include:

(A) An office used primarily for the private practice of a health care practitioner.

(B) A facility providing treatment solely on the basis of prayer or spiritual means in accordance with the tenets of any church or religious denomination.

(C) A facility conducted by a religious organization for the purpose of providing health care services exclusively to clergy or other persons in a religious profession who are members of a religious denomination.

*Health care practitioner*—An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.

*Health care provider*—An individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), the Commonwealth, or a political subdivision, or instrumentality (including a municipal corporation or authority) thereof, that operates a health care facility.

*Household contact*—A person living in the same residence as a case, including a spouse, child, parent, relation or other person, whether or not related to the case.

*Infectious agent*—Any organism, such as a virus, bacterium, fungus or parasite, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease.

*Isolation*—The separation for the communicable period of an infected person or animal from other persons or animals, in such a manner as to prevent the direct or indirect transmission of the infectious agent from infected persons or animals to other persons or animals who are susceptible or who may spread the disease to others.

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

*Local health authority*—A county or municipal department of health, or board of health of a municipality that does not have a department of health. The term includes a sanitary board.

*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).

*Local health officer*—The person appointed by a local health authority to head the daily administration of duties imposed upon or permitted of local health authorities by State laws and regulations.

*Medical record*—An account compiled by physicians and other health professionals including a patient's medical history; present illness; findings on physical examination; details of treatment; reports of diagnostic tests; findings and conclusions from special examinations; findings and diagnoses of consultants; diagnoses of the responsible physician; notes on treatment, including medication, surgical operations, radiation, and physical therapy; and progress notes by physicians, nurses and other health professionals.

*Modified quarantine*—A selected, partial limitation of freedom of movement determined on the basis of differences in susceptibility or danger of disease transmission which is designated to meet particular situations. The term includes the exclusion of children from school and the prohibition, or the restriction, of those exposed to a communicable disease from engaging in particular activities.

*Monitoring of contacts*—The close supervision of persons and animals exposed to a communicable disease without restricting their movement.

* * * * *

*Operator*—The legal entity that operates a child care group setting or a person designated by the legal entity to serve as the primary staff person at a child care group setting.

*Outbreak*—An unusual increase in the number of cases of a disease, infection or condition, whether reportable or not as a single case, above the number of cases that a person required to report would expect to see in a particular geographic area or among a subset of persons (defined by a specific demographic or other features).

*Physician*—An individual licensed to practice medicine or osteopathic medicine within this Commonwealth.

*Placarding*—The posting on a home or other building of a sign or notice warning of the presence of communicable disease within the structure and the danger of infection therefrom.

*Quarantine*—

(i) The limitation of freedom of movement of a person or an animal that has been exposed to a communicable disease, for a period of time equal to the longest usual incubation period of the disease, or until judged noninfectious by a physician, in a manner designed to prevent the direct or indirect transmission of the infectious agent from the infected person or animal to other persons or animals.

(ii) The term does not exclude the movement of a person or animal from one location to another when approved by the Department or a local health authority under § 27.67 (relating to the movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department).

*Reportable disease, infection, or condition*—A disease, infection, or condition, made reportable by § 27.2 (relating to specific identified reportable diseases, infections and conditions).

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*SHC—State Health Center*—The official headquarters of the Department in a county, other than a district office.

*Segregation*—The separation for special control or observation of one or more persons or animals from other persons or animals to facilitate the control of a communicable disease.

*Sexually transmitted disease*—A disease which, except when transmitted perinatally, is transmitted almost exclusively through sexual contact.

*Surveillance of disease*—The continuing scrutiny of all aspects of occurrence and spread of disease that are pertinent to effective control.

*Volunteer*—A person who provides services to a school or child care group setting without receiving remuneration.

**§ 27.2. Specific identified reportable diseases, infections and conditions.**

The diseases, infections and conditions in Subchapter B (relating to the reporting of diseases, infections and conditions) are reportable to the Department or the appropriate local health authority by the persons or entities in the manner and within the time frames set out in this chapter.

**§ 27.3. Reporting outbreaks and unusual diseases, infections and conditions.**

(a) A person required to report under this chapter shall report an outbreak within 24 hours, and in accordance with § 27.4 (relating to reporting cases).

(b) A person required to report under this chapter who suspects a public health emergency, shall report an unusual occurrence of a disease, infection or condition not listed as reportable in Subchapter B (relating to reporting of diseases, infections and conditions) or defined as an outbreak, within 24 hours, and in accordance with § 27.4.

(c) Any unusual or group expression of illness which the Department designates as a public health emergency shall be reported within 24 hours, and in accordance with § 27.4.

**§ 27.4. Reporting cases.**

(a) Except for reporting by a clinical laboratory, a case is to be reported to the LMRO serving the area in which a case is diagnosed or identified unless another provision of this chapter directs that a particular type of case is to be reported elsewhere. A clinical laboratory shall make reports to the appropriate office of the Department.

(b) Upon the Department's implementation of its electronic disease surveillance system for certain types of case reports, persons who make those reports shall do so electronically using an application and reporting format provided by the Department. At least 6 months in advance of requiring a type of case report to be reported electronically, the Department will publish a notice in the *Pennsylvania Bulletin* announcing when electronic reporting is to begin.

(c) This section does not prohibit a reporter from making an initial report of a case to the Department or an LMRO by telephone. The reporter will be instructed on how to make a complete case report at the time of the telephone call.

(d) Department offices to which this chapter requires specified case reports to be filed are as follows:

(1) Cancer Registry, Division of Health Statistics, Bureau of Health Statistics and Research.

(2) Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

(3) HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

(4) Division of Maternal and Child Health, Bureau of Family Health.

(e) A case shall be reported using the appropriate case report format. Information solicited by the case report form shall be provided by the reporter, irrespective of whether the report is made by submitting the form directly in hard copy or by telecommunication or electronic submission. An appropriate case report form or format may be procured from the office to which the type of case is reportable.

**§ 27.5. (Reserved).**

**§ 27.5a. Confidentiality of case reports.**

Case reports submitted to the Department or to an LMRO are confidential. Neither the reports, nor any information contained in them which identifies or is perceived by the Department or the LMRO as capable of being used to identify a person named in a report, will be disclosed to any person who is not an authorized employe or agent of the Department or the LMRO, and who has a legitimate purpose to access case information, except for any of the following reasons:

(1) When disclosure is necessary to carry out a purpose of the act, as determined by the Department or LMRO, and disclosure would not violate another act or regulation.

(2) When disclosure is made for a research purpose for which access to the information has been granted by the Department or an LMRO. Access shall be granted only when disclosure would not violate another act or regulation. The research shall be subject to strict supervision by the LMRO to ensure that the use of information disclosed is limited to the specific research purpose and will not involve the further disclosure of information which identifies or is perceived as being able to be used to identify a person named in a report.

**§ 27.6. Disciplinary consequences for violating reporting responsibilities.**

(a) Failure of a clinical laboratory to comply with the reporting provisions of this chapter may result in restrictions being placed upon or revocation of the laboratory's permit to operate as a clinical laboratory, as provided for in the Clinical Laboratory Act (35 P. S. §§ 2151—2165) unless failure to report is due to circumstances beyond the control of the clinical laboratory.

(b) Failure of a Department licensed health care facility to comply with the reporting provisions of this chapter may result in restrictions being placed upon or revocation of the health care facility's license, as provided for in the Health Care Facilities Act (35 P. S. §§ 448.101—448.904b).

(c) Failure of a health care practitioner to comply with the reporting provisions of this chapter may result in referral of that matter to the appropriate licensure board for disciplinary action.

(d) Failure of a child care group setting to comply with the reporting provisions of this chapter may result in referral of that matter to the appropriate licensing agency for appropriate action.

**§ 27.7. Cooperation between clinical laboratories and persons who order laboratory tests.**

To facilitate the reporting of cases by clinical laboratories, the following is required:

(1) When a clinical laboratory is requested to conduct a test which, depending upon the results, would impose a reporting duty upon the clinical laboratory, the clinical laboratory shall provide to the person who orders the testing, a form that solicits all information which is required for completion of the applicable case report form.

(2) A person who orders testing subject to paragraph (1) shall, at the time of ordering the test, provide the clinical laboratory with the information solicited by the form which that person either possesses or may readily obtain.

### § 27.8. Criminal penalties for violating the act or this chapter.

(a) A person who violates any provision of the act or this chapter shall, for each offense, upon conviction thereof in a summary proceeding before a district justice in the county wherein the offense was committed, be sentenced to pay a fine of not less than $25 and not more than $300, together with costs, and in default of payment of the fine and costs, shall be imprisoned in the county jail for a period not to exceed 30 days.

(b) A person afflicted with communicable tuberculosis, ordered to be quarantined or isolated in an institution, who leaves without consent of the medical director of the institution, is guilty of a misdemeanor, and upon conviction thereof, shall be sentenced to pay a fine of not less than $100 nor more than $500, or undergo imprisonment for not less than 30 days nor more than 6 months, or both.

(c) Prosecutions may be instituted by the Department, by a local health authority, or by any person having knowledge of a violation of the act or this chapter.

## Subchapter B. REPORTING OF DISEASES, INFECTIONS AND CONDITIONS

### GENERAL

### § 27.21. Reporting of AIDS cases by physicians and hospitals.

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 suspects, because of symptoms or the appearance of the individual, of having a reportable disease, infection or condition:

(1) A health care practitioner or health care facility is not required to report a case if that health care practitioner or health care facility has reported the case previously.

(2) A health care practitioner or health care facility is not required to report a case of influenza unless the disease is confirmed by laboratory evidence of the causative agent.

(3) A health care practitioner or health care facility is not required to report a case of chlamydia trachomatis infection unless the disease is confirmed by laboratory evidence of the infectious agent.

(4) A health care practitioner or health care facility is not required to report a case of cancer unless the health care practitioner or health care facility provides screening, therapy or diagnostic services to cancer patients.

(5) Only physicians and hospitals are required to report cases of AIDS.

(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:

(1) The following diseases, infections and conditions are reportable within 24 hours after being identified by symptoms, appearance or diagnosis:

Animal bite.

Anthrax.

Arboviruses.

Botulism.

Cholera.

Diphtheria.

Enterohemorrhagic E. coli.

Food poisoning outbreak.

Haemophilus influenzae invasive disease.

Hantavirus pulmonary syndrome.

Hemorrhagic fever.

Lead poisoning.

Legionellosis.

Measles (rubeola).

Meningococcal invasive disease.

Plague.

Poliomyelitis.

Rabies.

Smallpox

Typhoid fever.

(2) The following diseases, infections and conditions are reportable within 5 work days after being identified by symptoms, appearance or diagnosis:

AIDS.

Amebiasis.

Brucellosis.

Campylobacteriosis.

Cancer.

Chancroid.

Chickenpox (varicella) (effective January 26, 2005).

Chlamydia trachomatis infections.

Creutzfeldt-Jakob Disease.

Cryptosporidiosis.

Encephalitis.

Giardiasis.

Gonococcal infections.

Granuloma inguinale.

Guillain-Barre syndrome.

Hepatitis, viral, acute and chronic cases.

Histoplasmosis.

Influenza.

Leprosy (Hansen's disease).

Leptospirosis.

Listeriosis.

Lyme disease.

Lymphogranuloma venereum.

Malaria.

Maple syrup urine disease (MSUD) in children under 5 years of age.

Meningitis (All types not caused by invasive Haemophilus influenza or Neisseria meningitis).

Mumps.

Pertussis (whooping cough).

Phenylketonuria (PKU) in children under 5 years of age.

Primary congenital hypothyroidism in children under 5 years of age.

Psittacosis (ornithosis).

Rickettsial diseases.

Rubella (German measles) and congenital rubella syndrome.

Salmonellosis.

Shigellosis.

Sickle cell hemoglobinopathies in children under 5 years of age.

Staphylococcus aureus, Vancomycin-resistant (or intermediate) invasive disease.

Streptococcal invasive disease (group A).

Streptococcus pneumoniae, drug-resistant invasive disease.

Syphilis (all stages).

Tetanus.

Toxic shock syndrome.

Toxoplasmosis.

Trichinosis.

Tuberculosis, suspected or confirmed active disease (all sites).

Tularemia.

(c) A school nurse shall report to the LMRO any unusual increase in the number of absentees among school children. A caregiver at a child care group setting shall report to the LMRO any unusual increase in the number of absentees among children attending the child care group setting.

(d) A health care facility or health care practitioner providing screening, diagnostic or therapeutic services to patients with respect to cancer shall also report cases of cancer as specified in § 27.31 (relating to reporting cases of cancer).

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

(a) A person who is in charge of a clinical laboratory in which a laboratory examination of a specimen derived from a human body yields 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 was completed, except as otherwise noted in this chapter.

(b) The diseases, infections and conditions to be reported include the following:

Amebiasis.

Anthrax.

An unusual cluster of isolates.

Arboviruses

Botulism—all forms.

Brucellosis.

Campylobacteriosis.

Cancer.

Chancroid.

Chickenpox (varicella).

Chlamydia trachomatis infections.

Cholera.

Creutzfeldt-Jakob disease.

Cryptosporidiosis.

Diphtheria infections.

Enterohemorrhagic E. coli 0157 infections, or infections caused by other sub-types producing shiga-like toxin.

Giardiasis.

Gonococcal infections.

Granuloma inguinale.

Haemophilus influenzae infections—invasive from sterile sites.

Hantavirus.

Hepatitis, viral, acute and chronic cases.

Histoplasmosis.

Influenza.

Lead poisoning.

Legionellosis.

Leprosy (Hansen's disease).

Leptospirosis.

Listeriosis.

Lyme disease.

Lymphogranuloma venereum.

Malaria.

Maple syrup urine disease (MSUD) in children under 5 years of age.

Measles (rubeola).

Meningococcal infections—invasive from sterile sites.

Mumps.

Pertussis.

Phenylketonuria (PKU) in children under 5 years of age.

Primary congenital hypothyroidism in children under 5 years of age.

Plague.

Poliomyelitis.

Psittacosis (ornithosis).

Rabies.

Respiratory syncytial virus.

Rickettsial infections.

Rubella.

Salmonella.

Shigella.

Sickle cell hemoglobinopathies in children under 5 years of age.

Staphylococcus Aureus Vancomycin-resistant (or intermediate) invasive disease.

Streptococcus pneumoniae, drug-resistant invasive disease.

Syphilis.

Tetanus.

Toxoplasmosis.

Trichinosis.

Tuberculosis, confirmation of positive smears or cultures, including results of drug susceptibility testing.

Tularemia.

Typhoid.

(c) 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 by the person in charge of a laboratory, in either a hard copy format or an electronic transmission format specified by the Department.

(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 and lead poisoning shall be reported to the location specifically designated in this subchapter. See §§ 27.30, 27.31 and 27.34 (relating to reporting cases of certain diseases in the newborn child; reporting cases of cancer; and reporting cases of lead poisoning).

(f) 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) 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) 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) 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) 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 the 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, 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 time frames required in § 27.21a.

(1) Institutions maintaining dormitories and living rooms.

(2) Orphanages.

(3) Child care group settings.

**§ 27.24. (Reserved).**

**§ 27.24a. Reporting of cases by veterinarians.**

A veterinarian is required to report a case, as specified in § 27.4 (relating to reporting cases), only if the veterinarian treats or examines an animal which the veterinarian suspects of having a disease set forth in § 27.35(a) (relating to reporting cases of disease in animals).

**§§ 27.25—27.28. (Reserved).**

**§ 27.29. Reporting for special research projects.**

A person in charge of a hospital or other institution for the treatment of disease shall, upon request of the Department, make reports of a disease or condition for which the Board has approved a specific study to enable the Department to determine and employ the most efficient and practical means to protect and to promote the health of the people by the prevention and control of the disease or condition. The reports shall be made on forms prescribed by the Department and shall be transmitted to the Department or to local health authorities as directed by the Department.

## DISEASES AND CONDITIONS REQUIRING SPECIAL REPORTING

**§ 27.30. Reporting cases of certain diseases in the newborn child.**

Reports of maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism and sickle cell hemoglobinopathies shall be made to the Division of Maternal and Child Health, Bureau of Family Health, as specified in Chapter 28 (relating to metabolic diseases of the newborn) and those provisions of § 27.4 (relating to reporting cases) consistent with Chapter 28 and this section.

**§ 27.31. Reporting cases of cancer.**

(a) A hospital, clinical laboratory, or other health care facility providing screening, diagnostic or therapeutic services for cancer to cancer patients shall report each case of cancer to the Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and

Research, within 180 days of the patient's discharge, if an inpatient or, if an outpatient, within 180 days following diagnosis or initiation of treatment.

(b) A health care practitioner providing screening, diagnostic or therapeutic services to cancer patients for cancer shall report each cancer case to the Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and Research, within 5 work days of diagnosis. Cases directly referred to or previously admitted to a hospital or other health care facility providing screening, diagnostic or therapeutic services to cancer patients in this Commonwealth, and reported by those facilities, are exceptions and do not need to be reported by the health care practitioner.

(c) The Department or its authorized representative shall be afforded physical access to all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes and all other facilities, individuals or agencies providing services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer or medical status of any identified cancer patient.

(d) Reports submitted under this section are confidential and may not be open to public inspection or dissemination. Information for specific research purposes may be released in accordance with procedures established by the Department with the advice of the Pennsylvania Cancer Control, Prevention and Research Advisory Board.

(e) Case reports of cancer shall be sent to the Cancer Registry, Division of Health Statistics, Bureau of Health Statistics and Research, unless otherwise directed by the Department.

**§ 27.32. (Reserved).**

**§ 27.33. Reporting cases of sexually transmitted disease.**

(a) Reportable sexually transmitted diseases and infections are as follows:

(1) Chancroid.

(2) Chlamydia trachomatis infections.

(3) Gonococcal infections.

(4) Granuloma inguinale.

(5) Lymphogranuloma venereum.

(6) Syphilis.

(b) Health care practitioners and health care facilities shall make case reports of these diseases to the LMRO where the case is diagnosed or identified.

(c) A clinical laboratory making a case report by paper shall make the report to the LMRO where the case is diagnosed or idenitifed. A clinical laboratory making a case report electronically shall make the report to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

**§ 27.34. Reporting cases of lead poisoning.**

(a) *Reporting by clinical laboratories.*

(1) A clinical laboratory shall report all blood lead test results on both venous and capillary specimens for persons under 16 years of age to the Childhood Lead Poisoning Prevention Program, Division of Maternal and Child Health, Bureau of Family Health.

(2) A clinical laboratory shall report an elevated blood lead level in a person 16 years of age or older to the Division of Environmental Health Epidemiology, Bureau of Epidemiology or to other locations as designated by the Department. An elevated blood lead level is defined by the National Institute For Occupational Safety And Health (NIOSH). As of January 26, 2002, NIOSH defines an elevated blood lead level as a venous blood lead level of 25 micrograms per deciliter (µg/dL) or higher. The Department will publish in the *Pennsylvania Bulletin* any NIOSH update of the definition within 30 days of NIOSH's notification to the Department.

(3) A clinical laboratory which conducts blood lead tests of 100 or more specimens per month shall submit results electronically in a format specified by the Department.

(4) A clinical laboratory which conducts blood lead tests of less than 100 blood lead specimens per month shall submit results either electronically or by hard copy in the format specified by the Department.

(5) A laboratory which performs blood lead tests on blood specimens collected in this Commonwealth shall be licensed as a clinical laboratory and shall be specifically approved by the Department to conduct those tests.

(6) Blood lead analyses requested for occupational health purposes on blood specimens collected in this Commonwealth shall be performed only by laboratories which are licensed and approved as specified in paragraph (5), and which are also approved by the Occupational Safety and Health Administration of the United States Department of Labor under 29 CFR 1910.1025(j)(2)(iii) (relating to lead).

(7) A clinical laboratory shall complete a blood lead test within 5 work days of the receipt of the blood specimen and shall submit the case report to the Department by the close of business of the next work day after the day on which the test was performed. The clinical laboratory shall submit a report of lead poisoning using either the hard-copy form or electronic transmission format specified by the Department.

(8) When a clinical laboratory receives a blood specimen without all of the information required for reporting purposes, the clinical laboratory shall test the specimen and shall submit the incomplete report to the Department

(b) *Reporting by health care practitioners or health care facilities.* A health care practitioner or health care facility shall report all cases of lead poisoning for persons under 16 years of age and pregnant women to the Lead Poisoning Prevention Program, Child and Adult Health Services Division, Bureau of Family Health. A case of lead poisoning shall be a lead level of 20 µg/dL or greater or a persistent elevated blood lead level ( 2 or more venous blood lead levels of 15 to 19 µg/dL (inclusive) at least three months apart).

**§ 27.35. Reporting cases of disease in animals.**

(a) The following diseases, infections and conditions in animals are reportable to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology, as specified in § 27.4 (relating to reporting cases) within 5 work days after being identified:

Anthrax.

Arboviruses.

Brucellosis.

Plague.

Psittacosis.

Rabies.

Transmissible Spongiform Encephalopathies.

Tuberculosis.

Tularemia.

Any disease, infection or condition covered by § 27.3(b) (relating to reporting outbreaks and unusual diseases, infections and conditions.)

(b) This chapter applies only to animals having or suspected of having one of the diseases, infections or conditions listed in subsection (a).

## REPORTING BY LOCAL MORBIDITY REPORTING OFFICES

**§ 27.41. (Reserved).**

**§ 27.41a. Reporting by local morbidity reporting offices of case reports received.**

An LMRO that is not one of the Department's district offices shall report a case that has been reported to it to the district office for the State health district in which it is located, or to the central office when this chapter directs that reports are to be filed with that office.

**§ 27.42. (Reserved).**

**§ 27.42a. Reporting by local morbidity reporting offices of completed case investigations.**

An LMRO that is not one of the Department's district offices shall submit, on a weekly basis, a case investigation report of the information from each case investigation which has resulted in confirmation of the incidence of a reportable disease, infection or condition. The report shall be submitted to the appropriate Department office as follows in a format and within the length of time set forth in this chapter:

(1) *AIDS.* To the HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

(2) *Chickenpox, diphtheria, measles, mumps, pertussis, polio, rubella, and tetanus.* To the Division of Immunizations, Bureau of Communicable Diseases.

(3) *Chancroid, chlamydia trachomatis infections, gonococcal infections, granuloma inguinale, lymphogranuloma venereum, syphilis and tuberculosis.* To the Division of Tuberculosis and Sexually Transmitted Diseases, Bureau of Communicable Diseases.

(4) *Other reportable diseases and conditions.* To the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

**§ 27.43. (Reserved).**

**§ 27.43a. Reporting by local morbidity reporting offices of outbreaks and selected diseases.**

(a) An LMRO that is not one of the Department's district offices shall report an outbreak by telephone on the same day that the outbreak is reported or otherwise made known to it, as follows:

(1) *AIDS.* To the HIV/AIDS Epidemiology Section, Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

(2) *Chancroid, chlamydia trachomatis infections, gonococcal infections, granuloma inguinale, lymphogranuloma venereum, syphilis and tuberculosis.* To the Division of Tuberculosis and Sexually Transmitted Diseases, Bureau of Communicable Diseases.

(3) *Chickenpox, diphtheria, measles, mumps, pertussis, polio, rubella and tetanus.* To the Division of Immunizations, Bureau of Communicable Diseases.

(4) *Other reportable diseases and conditions.* To the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

(b) An LMRO that is not one of the Department's district offices shall report by telephone on the same day any of the following diseases is reported or otherwise made known to it, as follows:

(1) *Diphtheria, measles, pertussis and polio.* To the Division of Immunizations, Bureau of Communicable Diseases.

(2) *Anthrax, arbovirus disease, cholera, enterohemorrhagic Escherichia coli, hantavirus pulmonary syndrome, food borne botulism, Haemophilus influenzae invasive disease in a child under 15 years of age, hemorrhagic fever, hepatitis E, human rabies, Legionellosis, plague, smallpox, typhoid fever and yellow fever.* To the Division of Infectious Disease Epidemiology, Bureau of Epidemiology.

**§§ 27.44—27.47. (Reserved).**

**§ 27.51. (Reserved).**

## Subchapter C. QUARANTINE AND ISOLATION

## GENERAL PROVISIONS

**§ 27.60. Disease control measures.**

(a) The Department or local health authority shall direct isolation of a person or an animal with a communicable disease or infection; surveillance, segregation, quarantine or modified quarantine of contacts of a person or an animal with a communicable disease or infection; and any other disease control measure the Department or the local health authority considers to be appropriate for the surveillance of disease, when the disease control measure is necessary to protect the public from the spread of infectious agents.

(b) The Department and local health authority will determine the appropriate disease control measure based upon the disease or infection, the patient's circumstances, the type of facility available and any other available information relating to the patient and the disease or infection.

(c) If a local health authority is not an LMRO, it shall consult with and receive approval from the Department prior to taking any disease control measure.

**§ 27.61. Isolation.**

When the isolation of a person or animal that is suspected of harboring an infectious agent is appropriate, the Department or local health authority shall cause the isolation to be done promptly following receipt of the case report.

(1) If the local health authority is not an LMRO, the local health officer shall consult with and receive approval from the Department prior to requiring isolation.

(2) If more than one jurisdiction is involved, the local health officer shall cause a person or animal to be isolated only after consulting with and receiving approval from the Department.

(3) The Department or local health authority shall ensure that instructions are given to the case or persons responsible for the care of the case and to members of the household or appropriate living quarters, defining the area within which the case is to be isolated and identifying the measures to be taken to prevent the spread of disease.

**§§ 27.62—27.64. (Reserved).**

**§ 27.65. Quarantine.**

If the disease is one which the Department, or a local health authority which is also an LMRO, determines to require the quarantine of contacts in addition to isolation of the case, the Department or local health officer of the LMRO shall determine which contacts shall be quarantined, specify the place to which they shall be quarantined, and issue appropriate instructions.

(1) When any other local health authority is involved, the local health officer shall quarantine contacts only after consulting with and receiving approval from the Department.

(2) The Department or local health officer shall ensure that provisions are made for the medical observation of the contacts as frequently as necessary during the quarantine period.

**§ 27.66. Placarding.**

Whenever the Department or a local health officer has reason to believe that a case, a contact or others will not fully comply with the isolation or quarantine as required for the protection of the public health and the Department or local health officer deems it necessary to use placards, placards may be utilized. Placards may be utilized by a local health officer of a local health authority that is not an LMRO only if the specific use is approved by the Department.

**§ 27.67. Movement of persons and animals subject to isolation or quarantine by action of a local health authority or the Department.**

(a) A person or animal subject to isolation or quarantine by action of a local health authority or the Department may be removed to another location only with permission of the local health authority or the Department. If the local health authority is not an LMRO, the local health authority shall consult with and receive approval from the Department prior to permitting removal. Permission for removal may be given by the Department if the local health officer is not available.

(b) Removal of a person or animal under isolation or quarantine by action of the Department or a local health authority, from the jurisdiction of the Department or a local health authority to the jurisdiction of the Department or another local health authority may occur only with permission of the Department, if it is involved, and with the permission of the local health authorities concerned. If both of the local health authorities involved are not LMROs, the local health authorities shall consult with and receive approval from the Department prior to permitting removal. Permission for removal may be given by the Department if a local health officer from whom permission would otherwise be required is not available.

(c) Interstate transportation to or from this Commonwealth of a person or animal under isolation or quarantine may be made only with permission of the Department.

(d) Transportation of a person or animal under isolation or quarantine shall be made by private conveyance or as otherwise ordered by the local health authority or the Department. If the local health authority is not an LMRO, it shall consult with the Department prior to issuing an order. The sender, the receiver and the transporter of the person or animal shall be responsible to take due care to prevent the spread of the disease.

(e) When a person or animal under isolation or quarantine is transported, isolation or quarantine shall be resumed for the period of time required for the specific disease immediately upon arrival of the person or animal at the point of destination.

**§ 27.68. Release from isolation or quarantine.**

The Department or a local health authority may order that a person or animal isolated or quarantined under the direction of the Department or to the appropriate health authority be released from isolation or quarantine when the Department or the local health authority determines that the person or animal no longer presents a public health threat. If the local health authority involved is not an LMRO, it shall consult with, and receive approval from, the Department prior to making the order.

**§ 27.69. Laboratory analysis.**

Whenever a laboratory specimen is to be examined for the presence of etiologic organisms to determine the duration of isolation or quarantine or to determine the eligibility of a person or animal for release from isolation or quarantine, the specimen shall be examined in a laboratory approved by the Department to conduct that type of examination.

**COMMUNICABLE DISEASES IN CHILDREN AND STAFF ATTENDING SCHOOLS AND CHILD CARE GROUP SETTINGS**

**§ 27.71. Exclusion of children, and staff having contact with children, for specified diseases and infectious conditions.**

A person in charge of a public, private, parochial, Sunday or other school or college shall exclude from school a child, or a staff person, including a volunteer, who has contact with children, who is suspected by a physician or the school nurse of having any of the communicable diseases, infections or conditions. Readmission shall be contingent upon the school nurse or, in the absence of the school nurse, a physician, verifying that the criteria for readmission have been satisfied. The diseases, the periods of exclusion and the criteria for readmission are as follows:

(1) *Diphtheria.* Two weeks from the onset or until appropriate negative culture tests.

(2) *Measles.* Four days from the onset of rash. Exclusion may also be ordered by the Department as specified in § 27.160 (relating to special requirements for measles).

(3) *Mumps.* Nine days from the onset or until subsidence of swelling.

(4) *Pertussis.* Three weeks from the onset or 5 days from institution of appropriate antimicrobial therapy.

(5) *Rubella.* Four days from the onset of rash.

(6) *Chickenpox.* Five days from the appearance of the first crop of vesicles, or when all the lesions have dried and crusted, whichever is sooner.

(7) *Respiratory streptococcal infections including scarlet fever.* At least 10 days from the onset if no physician is in attendance or 24 hours after institution of appropriate antimicrobial therapy.

(8) *Infectious conjunctivitis (pink eye).* Until judged not infective; that is, without a discharge.

(9) *Ringworm.* The person shall be allowed to return to school, child care or other group setting immediately after the first treatment, if body lesions are covered. Neither scalp nor body lesions that are dried need to be covered.

(10) *Impetigo contagiosa.* Twenty-four hours after the institution of appropriate treatment.

(11) *Pediculosis capitis.* The person shall be allowed to return to either the school, child care or other group setting immediately after first treatment. The person shall be reexamined for infestation by the school nurse, or other health care practitioner, 7 days posttreatment.

(12) *Pediculosis corpora.* After completion of appropriate treatment.

(13) *Scabies.* After completion of appropriate treatment.

(14) *Trachoma.* Twenty-four hours after institution of appropriate treatment.

(15) *Tuberculosis.* Following a minimum of 2 weeks adequate chemotherapy and three consecutive negative morning sputum smears, if obtainable. In addition, a note from the attending physician that the person is noncommunicable shall be submitted prior to readmission.

(16) *Neisseria meningitidis.* Until judged noninfective after a course of rifampin or other drug which is effective against the nasopharyngeal carriage state of this disease, or until otherwise shown to be noninfective.

**§ 27.72. Exclusion of children, and staff having contact with children, for showing symptoms.**

(a) A person in charge of a public, private, parochial, Sunday or other school or college shall, following consultation with a physician or school nurse, exclude immediately a child, or staff person, including a volunteer, having contact with children, showing any of the following symptoms, unless that person is determined by the school nurse, or a physician, to be noncommunicable:

(1) Mouth sores associated with inability to control saliva.

(2) Rash with fever or behavioral change.

(3) Purulent discharge from the eyes.

(4) Productive cough with fever.

(5) Oral or axillary temperature equal to or greater than 102° F.

(6) Unusual lethargy, irritability, persistent crying, difficulty breathing or other signs of severe illness.

(7) Persistent vomiting.

(8) Persistent diarrhea.

(b) The school shall maintain a record of the exclusion and the reasons prompting the exclusion and shall review the record to determine when unusual rates of absenteeism occur.

**§ 27.73. Readmission of excluded children, and staff having contact with children.**

(a) A child or staff person, including a volunteer, having contact with children, excluded from a public, private, parochial or other school or college under § 27.72 (relating to exclusion of children, and staff having contact with children, for showing symptoms) may not be readmitted until the school nurse or, in the absence of a school nurse, a physician, is satisfied that the condition for which the person was excluded is not communicable or until the person presents a statement from a physician that the person has recovered or is noninfectious.

(b) A child, or staff person, including a volunteer, having contact with children, excluded for the following reasons shall be readmitted only when a physician has determined the illness to be either resolved, noncommunicable or in a noncommunicable stage:

(1) Rash with fever or behavioral change.

(2) Productive cough with fever.

**§ 27.74. Readmission of exposed or isolated children, and staff having contact with children.**

A child, or staff person, including a volunteer, having contact with children, who has been absent from school by reason of having had or because of residing on premises where there has been a disease for which isolation is required, may not be readmitted to school without the permission of the LMRO.

**§ 27.75. Exclusion of children, and staff having contact with children, during a measles outbreak.**

Children, and staff, including a volunteer, having contact with children, shall be excluded from school during a measles outbreak under the procedures described in § 27.160 (relating to special requirements for measles).

**§ 27.76. Exclusion and readmission of children, and staff having contact with children, in child care group settings.**

(a) Sections 27.71—27.75 apply to child care group settings, with the exception that readmission of excluded persons as provided in those sections, as well as provided in this subsection, shall be contingent upon a physician verifying that the criteria for readmission have been satisfied. The following conditions and circumstances also govern exclusion from and readmission to a child care group setting of a child, or a staff person, including a volunteer, who has contact with children attending the child care group setting:

(1) *Meningococcal meningitis or meningococcemia.* Until made noninfective by a course of rifampin or other drug which is effective against the nasopharyngeal carriage stage of this disease, or otherwise shown to be noninfective.

(2) *Haemophilus influenzae (H. flu) meningitis or other invasive H. flu disease.* Until made noninfectious by a course of rifampin or other drug which is effective against the nasopharyngeal carriage stage of this disease, or otherwise shown to be noninfective.

(3) *Persistent diarrhea.* Until resolved or judged to be noninfective when associated with any of the following:

(i) Inability to prevent contamination of the environment with feces.

(ii) Fever.

(iii) Identified bacterial or parasitic pathogen.

(4) *Fever in children younger than 4 months of greater than 101° F. rectally or 100° F. axillary; in children 4-24 months of greater than 102° F. rectally or 101° F. axillary.* Until resolved or judged to be noninfective.

(5) *Hepatitis A, viral hepatitis unspecified, or jaundice of unspecified etiology.* Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present.

(6) *Shigellosis.* Until the etiologic organism is eradicated. See § 27.158 (relating to special requirements for shigellosis).

(7) *Typhoid fever or paratyphoid fever.* Until the etiologic organism is eradicated. See § 27.159 (relating to special requirements for typhoid and paratyphoid fever).

(8) *Exposure to an individual with meningococcal disease.* Until the institution of treatment with appropriate antibiotic to eradicate the nasopharyngeal carrier state, or until proven noninfectious with nasopharyngeal cultures, or until 30 days following the exposure. Exclusion shall be postponed, until the second day following notice that exclusion will be required, to give the individual sufficient time to arrange for institution of appropriate antibiotic treatment.

(b) To facilitate the proper exclusion of sick children and staff, the caregiver at a child care group setting shall arrange for the following:

(1) Instruction of staff, including volunteers, regarding exclusion and screening criteria that apply to themselves and attending children.

(2) Instruction of parents and guardians regarding exclusion criteria and that they are to notify the caregiver within 24 hours after it is determined or suspected that a child has an illness or condition for which exclusion is required.

(3) Followup after exclusion of a child by staff at the time the child is brought to the child care group setting to ensure that the condition which required exclusion has been resolved.

**§ 27.77. Immunization requirements for children in child care group settings.**

(a) *Caregiver responsibilities.*

(1) Except as exempted in subsection (d), effective March 27, 2002, the caregiver at a child care group setting may not accept or retain a child 2 months of age or older at the setting, for more than 60 days, unless the caregiver has received a written objection to a child being vaccinated on religious grounds from a parent or guardian, or one of the following:

(i) For all children not exempt under subsection (d)(1)(ii), an initial written verification from a physician, the Department or a local health department of the dates (month, day and year) the child was administered any vaccines recommended by ACIP. The verification shall also specify any vaccination not given due to medical condition of the child and shall state whether the condition is temporary or permanent. The verification shall show compliance with the vaccination requirements in subsection (b).

(ii) For all children for whom vaccinations remain outstanding following the caregiver's receipt of the initial written verification, subsequent written verifications from a physician, the Department or a local health department as additional vaccinations become due. These verifications shall be prepared in the same manner as set forth in subparagraph (i), but need not repeat information contained in a previously submitted verification. The verifications shall demonstrate continuing compliance with the vaccination requirements in subsection (b).

(2) If the caregiver receives a written verification under paragraph (1) explaining that timely vaccination did not occur due to a temporary medical condition, the caregiver shall exclude the child from the child care group setting after an additional 30 days unless the caregiver receives, within that 30-day period, written verification from a physician, the Department or a local health department that the child was vaccinated or that the temporary medical condition still exists. If the caregiver receives a written verification that vaccination has not occurred because the temporary condition persists, the caregiver shall require the presentation of a new verification at 30-day intervals. If a verification is not received as required, the caregiver shall exclude the child from the child care group setting and not readmit the child until the caregiver receives a verification that meets the requirements of this section.

(3) The caregiver shall retain the written verification or objection referenced in paragraphs (1) and (2) for 60 days following the termination of the child's attendance.

(4) The caregiver shall ensure that a certificate of immunization is completed and signed for each child enrolled in the child care group setting. The certificates shall be updated by the caregiver to include the information provided to the caregiver under subsection (a) when that additional information is received. The immunization status of each enrolled child shall be summarized and reported on an annual basis to the Department at the time prescribed by the Department and on the form provided by the Department.

(b) *Vaccination requirements.* Each child enrolled in a child care group setting shall be immunized in accordance with ACIP standards in effect on January 1, 1999, governing the issuance of ACIP recommendations for the immunization of children.

(1) The standards are as follows:

(i) The immunization practice is supported by both published and unpublished scientific literature as a means to address the morbidity and mortality of the disease.

(ii) The labeling and packaging inserts for the immunizing agent are considered.

(iii) The immunizing agent is safe and effective.

(iv) The schedule for use of the immunizing agent is administratively feasible.

(2) The Department will deem an ACIP recommendation pertaining to the immunization of children to satisfy the standards in this subsection unless ACIP alters its standards for recommending immunizations for children by eliminating a standard set forth in this subsection and the recommendation is issued under those changed standards.

(c) *Notice.* The Department will place a notice in the *Pennsylvania Bulletin* listing publications containing ACIP recommendations issued under the standards in subsection (b). The Department will publish the initial notice at 32 Pa.B. 539 (January 26, 2002), contemporaneously with the adoption of amendments to this chapter. The Department will update that list in a notice which it will publish in the *Pennsylvania Bulletin* within 30 days after ACIP issues a recommendation which satisfies the criteria of this section.

(d) *Exemptions.*

(1) This section does not apply to the following:

(i) Kindergarten, elementary school or higher school. These caregivers shall comply with §§ 23.81—23.87 (relating to immunization).

(ii) Children who are known by the caregiver to be 6 years of age or older or to attend a kindergarten, elementary school or high school.

(iii) A caregiver who does not serve as a caregiver for at least 40 hours during at least 1 month.

(2) The requirement imposed by subsection (a), to not accept a child into a child care group setting without receiving an initial written verification or objection speci-

fied in subsection (a), does not apply during a month the caregiver does not serve as a caregiver for at least 40 hours.

(e) *Exclusion when disease is present.* Whenever one of the diseases in § 27.76 (relating to exclusion and readmission of children, and staff having contact with children, in child care group settings) has been identified within a child care group setting, the Department or a local health department may order the exclusion from the child care group setting or any other child care group setting which is determined to be at high-risk of transmission of that disease, of an individual susceptible to that disease in accordance with public health standards as determined by the Department.

## Subchapter D. SEXUALLY TRANSMITTED DISEASES, TUBERCULOSIS AND OTHER COMMUNICABLE DISEASES

### § 27.81. Examination of persons suspected of being infected.

Whenever the Department or a local health authority has reasonable grounds to suspect a person of being infected with an organism causing a sexually transmitted disease, tuberculosis or other communicable disease, or of being a carrier, but lacks confirmatory medical or laboratory evidence, the Department or the local health authority may require the person to undergo a medical examination and any other approved diagnostic procedure to determine whether or not the person is infected or is a carrier. If the local health authority involved is not an LMRO, the local health authority shall consult with and receive approval from the Department prior to requiring any medical examination or other approved diagnostic procedure.

### § 27.82. Refusal to submit to examination.

(a) If a person refuses to submit to the examination required in § 27.81 (relating to examination of persons suspected of being infected), the Department or the local health authority may direct the person to be quarantined until it is determined that the person does not pose a threat to the public health by reason of being infected with a disease causing organism or being a carrier.

(b) If the person refuses to abide by an order issued under subsection (a), the Department or local health authority may file a petition in the court of common pleas of the county in which the person is present. The petition shall have a statement attached, given under oath by a physician licensed to practice in this Commonwealth, that the person is suspected of being infected with an organism causing a sexually transmitted disease, tuberculosis or other communicable disease, or that the person is suspected of being a carrier.

(1) Upon the filing of the petition, the court shall, within 24 hours after service of a copy upon the respondent, hold a hearing without a jury to ascertain whether the person named in the petition has refused to submit to an examination to determine whether the person is infected with the suspected disease causing organism, or that the person is a carrier.

(2) Upon a finding that the person has refused to submit to an examination and that there is no valid reason for the person to do so, the court may forthwith order the person to submit to the examination.

(3) The certificate of the physician attached to the petition shall be received in evidence and shall constitute prima facie evidence that the person named is suspected of being infected with the disease causing organism, or that the person is a carrier.

(c) A person refusing to undergo an examination as required under subsections (a) and (b) may be committed by the court to an institution in this Commonwealth determined by the Department to be suitable for the care of persons infected with the suspected disease causing organism.

### § 27.83. Court ordered examinations.

The examination ordered by the court under § 27.82 (relating to refusal to submit to examination) may be performed by a physician chosen by the person at the person's own expense. The examination shall include an appropriate physical examination and laboratory tests performed in a clinical laboratory approved by the Department to conduct the tests, and shall be conducted in accordance with accepted professional practices. The results shall be reported to the local health authority or the Department on case report forms furnished by the Department.

### § 27.84. Examination for a sexually transmitted disease of persons detained by police authorities.

(a) A person taken into custody and charged with a crime involving lewd conduct or a sex offense, or a person to whom the jurisdiction of a juvenile court attaches may be examined for a sexually transmitted disease by a qualified physician appointed by the Department, by the local health authority or by the court having jurisdiction over the person so charged. If the person refuses to permit an examination or provide a specimen for laboratory tests as requested by the physician designated by the Department, a local health authority or a court, judicial action may be pursued by the Department or local health authority to secure an appropriate remedy.

(b) A person convicted of a crime or pending trial, who is confined in or committed to a State or local penal institution, reformatory or other house of correction or detention, may be examined for a sexually transmitted disease by a qualified physician appointed by the Department or by the local health authority. If the person refuses to permit an examination or provide a specimen for laboratory tests as requested by the physician, judicial action may be pursued by the Department or local health authority to secure an appropriate remedy.

(c) A person described in subsection (a) or (b) found, upon examination, to be infected with a sexually transmitted disease shall be given appropriate treatment by the local health authority, the Department or the attending physician of the institution.

### § 27.85. Diagnosis and treatment of a sexually transmitted disease.

(a) The Department will provide or designate adequate facilities for the free diagnosis and, where necessary for the preservation of public health, free treatment of persons infected with sexually transmitted diseases.

(b) Upon approval of the Department, a local health authority shall undertake to share the expense of furnishing free diagnosis and free treatment of a sexually transmitted disease, or shall furnish free diagnosis and free treatment of the sexually transmitted disease without financial assistance from the Department.

### § 27.86. (Reserved).

### § 27.87. Refusal to submit to treatment for communicable diseases.

(a) If the Department or a local health authority finds that a person who is infected with a sexually transmitted disease, tuberculosis or other communicable disease in a

communicable stage refuses to submit to treatment approved by the Department or by a local health authority, the Department or the local health authority, if it determines the action advances public health interests, shall order the person to be isolated in an appropriate institution designated by the Department or by the local health authority for safekeeping and treatment until the disease has been rendered noncommunicable.

(i) If the disease is one which may be significantly reduced in its communicability following short-term therapy, but is likely to significantly increase in its communicability if that therapy is not continued, such as tuberculosis, the Department or local health authority may order the person to complete therapy which is designed to prevent the disease from reverting to a communicable stage, including completion of an inpatient treatment regimen. See, also, § 27.161 (relating to special requirements for tuberculosis).

(ii) If the local health authority involved is not an LMRO, the local health authority shall consult with and receive approval from the Department prior to taking any action under this subsection.

(b) If a person refuses to comply with an order issued under subsection (a), the Department or local health authority may file a petition in the court of common pleas of the county in which the person is present to commit the person to an appropriate institution designated by the Department or by the local health authority for safekeeping and treatment as specified in subsection (a). Upon the filing of a petition, the court shall, within 24 hours after service of a copy upon the respondent, hold a hearing without a jury to ascertain whether the person named in the petition has refused to submit to treatment. Upon a finding that the person has refused to submit to treatment, the court shall issue an appropriate order.

(c) For the purpose of this section, treatment approved by the Department or by a local health authority may include treatment by an accredited practitioner of a well recognized church or religious denomination which relies on prayer or spiritual means alone for healing, if requirements relating to sanitation, isolation or quarantine are satisfied.

**§ 27.88. Isolation and quarantine in appropriate institutions.**

(a) When the Department or a local health authority orders a person with or suspected of having a sexually transmitted disease to be isolated or quarantined for the purpose of safekeeping and treatment, it may order that the isolation or quarantine take place in an institution where the person's movement is physically restricted.

(b) The Department or the local health authority shall reimburse an institution which accepts the person at the rate of maintenance that prevails in the institution, and shall furnish the necessary medical treatment to the person isolated or quarantined within the institution.

**§ 27.89. Examinations for syphilis.**

(a) *Prenatal examination for syphilis.*

(1) *Blood sample.*

(i) A physician who attends, treats or examines a pregnant woman for conditions relating to pregnancy during the period of gestation or delivery shall inform the woman that he intends to take or cause to be taken, unless the woman objects, a sample of her blood at the time of the first examination (including the initial visit when a pregnancy test is positive), or within 15 days after the first examination, and shall submit the sample to a clinical laboratory for an approved test for syphilis.

(ii) A physician shall similarly collect and have tested a sample of the pregnant woman's blood during the third trimester of her pregnancy, in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions.

(iii) The Department will publish the list of those counties in which this rate is occurring in the *Pennsylvania Bulletin* as necessary.

(iv) Other persons permitted by law to attend pregnant women, but not permitted by law to take blood samples, shall, unless the woman objects, cause a blood sample to be taken and submitted to a clinical laboratory for an approved test for syphilis.

(v) If the pregnant woman objects, it shall be the duty of the person attending the pregnant woman and seeking to have the woman give a blood sample to explain to her the desirability of the test.

(2) *Charge for test.* The serological test required by paragraph (1) will be made without charge, by the Department, upon the request of the physician submitting the blood sample and the submission of a certificate by the physician that the patient is unable to pay.

(b) *Examination for syphilis in mother of newborn.* A test for syphilis shall be done, unless the mother objects, on the blood of the mother of every newborn delivered in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions.

(1) The Department will publish the list of counties in which this rate is occurring in the *Pennsylvania Bulletin* as necessary.

(2) The results of the test shall be recorded both in the mother's medical record and in the newborn's medical record prior to discharge.

(c) *Examination for syphilis in mother of stillborn.*

(i) A test for syphilis shall be done, unless the mother objects, on the blood of the mother of every stillborn child delivered in those counties of this Commonwealth where the annual rate of infectious syphilis is at a rate of syphilis occurring in a given population for which the CDC has determined it is cost-effective to require special precautions.

(ii) The Department will publish the list of counties in which this rate is occurring in the *Pennsylvania Bulletin* as necessary.

(iii) The Department will be responsible for alerting physicians about this standard.

(iv) The blood shall be collected within 2 hours after delivery and the result entered into the mother's medical record prior to discharge. See also, § 27.95 (relating to reporting syphilis examination information for births and fetal deaths).

**§§ 27.90—27.94. (Reserved).**

**§ 27.95. Reporting syphilis examination information for births and fetal deaths.**

In reporting a birth or fetal death, physicians and others required to make the reports shall state in the medical record whether or not the blood tests required by

§ 27.89(b) (relating to examinations for syphilis) were made. If a test was made, the date of the test shall be given, and if a test was not made, the reason the test was not made shall be given.

**§ 27.96. Diagnostic tests for sexually transmitted diseases.**

(a) When testing for a sexually transmitted disease is required by the act or this chapter, the test used shall be a test approved by the Food and Drug Administration, and if a laboratory test is part of the approved procedure, it shall be conducted in a clinical laboratory approved by the Department to perform the test.

(b) The diagnostic tests that have been approved to test for each sexually transmitted disease may be ascertained by contacting the Division of Clinical Microbiology, Bureau of Laboratories.

**§ 27.97. Treatment of minors.**

A person under 21 years of age may give consent for medical and other health services to determine the presence of or to treat a sexually transmitted disease and any other reportable disease, infection or condition. If the minor consents to undergo diagnosis or treatment, approval or consent of another person is not necessary. The physician may not be sued or held liable for implementing appropriate diagnostic measures or administering appropriate treatment to the minor if the minor has consented to the procedures or treatment.

**§ 27.98. Prophylactic treatment of newborns.**

(a) Physicians and midwives attending women in childbirth shall instill in each eye of the newborn child, as soon as practicable after birth, either a 1% silver nitrate solution, or erythromycin ophthalmic ointment or solution as a single application in both conjunctival sacs, or appropriate medication approved by the Department.

(b) If the parent or guardian of the newborn child objects on the ground that the prophylactic treatment conflicts with the parent's or guardian's religious beliefs or practices, or if in the opinion of the attending physician treatment is not advisable, prophylactic treatment shall be withheld.

(c) An entry in the child's hospital record indicating the reason for withholding treatment shall be made and signed by the attending physician and the parent or guardian.

**§ 27.99. Prenatal examination for hepatitis B.**

(a) A physician who attends, treats or examines a pregnant woman for conditions relating to pregnancy during the period of gestation or delivery, shall inform the woman that the physician intends to take or cause to be taken, unless the woman objects, a sample of her blood at the time of the first examination (including the initial visit when a pregnancy test is positive) or within 15 days thereafter, but no later than the time of delivery, and shall submit the sample to a clinical laboratory approved by the Department to conduct immunologic testing.

(b) When a pregnant woman tests positive for hepatitis B surface antigen, a physician shall provide the appropriate prophylactic treatment to the newborn within 12 hours after birth. If the parent or guardian of the newborn child objects on the ground that the prophylactic treatment conflicts with the parent's or guardian's religious beliefs or practices, prophylactic treatment shall be withheld, and an entry in the child's hospital record indicating the reason for withholding treatment shall be made and signed by the attending physician and the parent or guardian.

## Subchapter E. SELECTED PROCEDURES FOR PREVENTING DISEASE TRANSMISSION

**§§ 27.101—27.146. (Reserved).**

**§ 27.151. Restrictions on the donation of blood, blood products, tissue, sperm and ova.**

(a) A person known to be, or suspected of being, infected with the causative agent of a reportable disease is not allowed to donate blood, blood products, tissue, sperm or ova for use in other human beings.

(1) In addition, a person or entity may not accept any of these materials from a person known to be, or suspected of being, infected with the causative agent of a reportable disease for donation without obtaining laboratory evidence showing the absence of hepatitis B, hepatitis C, HIV or other diseases and infections, which the Department may specify by placing a notice in the *Pennsylvania Bulletin*.

(2) The list of additional diseases and conditions will not remain in effect for more than 90 days after publication unless the Board acts to affirm it within that 90-day period.

(b) The only exception to a person or entity accepting donations without obtaining laboratory evidence showing the absence of diseases and infections designated by the Department is when the delay that would be necessary to properly test the blood of the donor would threaten the recipient's survival.

**§ 27.152. Investigation of cases and outbreaks.**

(a) The Department or a local health authority may investigate any case or outbreak of disease judged by the Department or local health authority to be a potential threat to the public health.

(b) A person may not interfere with or obstruct a representative of the Department or a local health authority who seeks to enter a house, health care facility, building or other premises to carry out an investigation of a case or outbreak, if the representative presents documentation to establish that he is an authorized representative of the Department or the local health authority.

(c) In the course of conducting an investigation of a case or outbreak, the authorized representative of the Department or local health authority may conduct a confidential review of medical records. A person may not interfere with or obstruct this review.

**§ 27.153. Restrictions on food handlers.**

A person with the following diseases or conditions may not work as a food handler, see, also, 3 Pa.C.S. Chapter 65 (relating to the Food Employee Certification Act) and 7 Pa. Code §§ 78.41—78.43 (relating to health and disease control of employees), except as follows:

(1) *Amebiasis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antiparasitic treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.156 (relating to the special requirements for amebiasis).

(2) *Enterohemorrhagic E. coli.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner

than 48 hours after treatment was completed. See § 27.157 (relating to the special requirements for enterohemorrhagic E. coli).

(3) *Shigellosis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.158 (relating to the special requirements for shigellosis).

(4) *Typhoid fever or paratyphoid fever.* Until the etiologic organism has been eradicated as proven by three negative successive stool specimens collected at intervals of at least 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. See § 27.159 (relating to the special requirements for typhoid and paratyphoid fever).

(5) *Hepatitis A, viral hepatitis, or jaundice of unspecified etiology.* Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician.

(6) *Persistent diarrhea.* Until resolved or judged to be noninfective by a physician.

**§ 27.154. Restrictions on caregivers in a child care group setting.**

A person with the following diseases or conditions may not work as a care giver in a child care group setting if the caregiver attends or works in a capacity which requires direct contact with children except as follows:

(1) *Amebiasis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.156 (relating to the special requirements for amebiasis).

(2) *Enterohemorrhagic E. coli.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.157 (relating to the special requirements for enterohemorrhagic E. coli).

(3) *Shigellosis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.158 (relating to the special requirements for shigellosis).

(4) *Typhoid fever or paratyphoid fever.* Until the etiologic organism is eradicated as proven by three negative successive stool specimens collected at intervals of no less than 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. See § 27.159 (relating to the special requirements for typhoid and paratyphoid fever).

(5) *Hepatitis A, viral hepatitis or jaundice of unspecified etiology.* Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician.

(6) *Persistent diarrhea.* Until resolved or judged to be noninfective by a physician.

**§ 27.155. Restrictions on health care practitioners.**

Persons with the following diseases or conditions may not work as health care practitioners who provide direct patient care:

(1) *Amebiasis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antiparasitic treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.156 (relating to the special requirements for amebiasis).

(2) *Enterohemorrhagic E. coli.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given, the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.157 (relating to the special requirements for enterohemorrhagic E. coli).

(3) *Shigellosis.* Until the etiologic organism is eradicated as proven by two consecutive negative stool specimens, obtained at least 24 hours apart, as verified by a physician. If antibacterial treatment has been given the specimens may not be collected sooner than 48 hours after treatment was completed. See § 27.158 (relating to the special requirements for shigellosis).

(4) *Typhoid fever or paratyphoid fever.* Until the etiologic organism is eradicated as proven by three negative successive stool specimens collected at intervals of no less than 24 hours nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi or paratyphi, and no earlier than 1 month after onset. See § 27.159 (relating to the special requirements for typhoid or paratyphoid fever).

(5) *Hepatitis A, viral hepatitis or jaundice of unspecified etiology.* Until 1 week following the onset of jaundice, or 2 weeks following symptom onset or IgM antibody positivity if jaundice is not present, as verified by a physician.

(6) *Persistent diarrhea.* Until resolved or judged to be noninfective by a physician.

**§ 27.156. Special requirements for amebiasis.**

A household contact of a case of amebiasis who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antiparasitic therapy, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Entamoeba histolytica.

**§ 27.157. Special requirements for enterohemorrhagic E. coli.**

A household contact of a case of enterohemorrhagic E. coli, who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antimicrobial

therapy, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for enterohemorrhagic E. coli.

**§ 27.158. Special requirements for shigellosis.**

A household contact of a case of shigellosis, who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two consecutive stool specimens, taken at least 24 hours apart and at least 48 hours after the last dose of any antimicrobial therapy, to an appropriate clinical laboratory for bacteriologic examination and the specimens are determined by the laboratory to be negative for shigella.

**§ 27.159. Special requirements for typhoid and paratyphoid fever.**

(a) An asymptomatic household contact of a case of typhoid fever or paratyphoid fever who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which requires contact with children, or who provides direct patient care shall be required to cease work until the contact has submitted two stool specimens, taken at least 24 hours apart, to an appropriate clinical laboratory for bacteriologic examination and those specimens are determined by the laboratory to be negative for Salmonella typhi or Salmonella paratyphi.

(b) A symptomatic household contact of a case of typhoid or paratyphoid fever who prepares or serves food for public consumption, who attends or works in a child care group setting in a capacity which involves contact with children, or who provides direct patient care shall be required to cease work until bacteriologic examination of three consecutive stool specimens, taken at least 24 hours apart and no sooner than 48 hours after any microbial therapy, and no earlier than 1 month after onset, are reported as negative.

(c) A chronic carrier of typhoid or paratyphoid fever shall be excluded from preparing or serving food for public consumption, attending or working in a child care group setting in a capacity which involves contact with children, and providing direct patient care, until three consecutive negative fecal cultures are obtained from specimens taken at least 1 month apart and at least 48 hours after antibiotic therapy has stopped.

**§ 27.160. Special requirements for measles.**

(a) *Isolation.* An infected person shall be restricted to the premises for 4 days after the appearance of the rash.

(b) *Quarantine.* Whenever measles is determined to be present in a school or child care group setting population, the Department or a local health department may do the following:

(1) Ascertain which children and staff persons are presumed susceptibles. A presumed susceptible is a person who fits into all of the following categories:

(i) Presents no history of two doses of measles vaccination, separated by at least 1 month, while 12 months of age or older.

(ii) Does not demonstrate serological evidence of measles immunity. The serological evidence is the presence of antibody to measles determined by the hemagglutination inhibition test or a comparable test.

(iii) Was born after December 31, 1956.

(2) Order exclusion from the school or child care group setting of presumed susceptible children and staff persons who do not present evidence of having received measles vaccination within 30 days prior to the outbreak. Exclusion shall continue until the excluded persons prove they do not meet the exclusion criteria in paragraph (1), they receive a measles vaccination, or no case of measles has occurred for a 14-day period.

**§ 27.161. Special requirements for tuberculosis.**

(a) *Isolation.* A person suspected of having tuberculosis in its communicable stage shall be isolated in the following manner:

(1) Isolation for tuberculosis shall be established at the usual residence of the person suffering from tuberculosis whenever facilities for adequate isolation of the infectious person are available at the residence, if the person will accept the isolation. Isolation of a person treated at a residence shall include instruction in the need to cover the mouth and nose when coughing and sneezing, and careful handling and disposal of sputum.

(2) If isolation for tuberculosis cannot be accomplished or maintained at the usual residence of the person and whenever, in the opinion of the Department or local health authority, the person is a health threat to others, by reason of the person's habits, neglect of treatment or noncompliance with the measures designed to protect others from infection, the isolation shall be enforced by following the procedures in § 27.87 (relating to refusal to submit to treatment for communicable diseases).

(i) Isolation of a person treated in an appropriate institution shall be in accordance with *CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* and any updates thereto as approved by the Board.

(ii) The Department will publish notice in the *Pennsylvania Bulletin* of updates of this publication within 30 days after Board approval is obtained.

(b) *Handling of contacts.* A human household contact or other close human contact shall be required to have a Mantoux tuberculin test or chest X-ray, or both. A close human contact means a person who spends a substantial amount of time with a person who has infectious tuberculosis. If the person refuses, enforcement shall be accomplished as designated in §§ 27.82 and 27.83 (relating to request to submit to examination; and court ordered examinations). If evidence of tuberculosis in contacts is found on chest X-rays or by symptoms, laboratory studies shall be conducted to determine if the contacts represent a public health threat.

**§ 27.162. Special requirements for animal bites.**

Except as may be otherwise required by the Dog Law (3 P. S. §§ 459-101—459-1205) and regulations promulgated by the Department of Agriculture in 7 Pa. Code Chapters 21, 23, 25 and 27 quarantine of a biting animal shall conform to the following:

(1) When an animal bites or otherwise potentially exposes a human to rabies, the Department or local health authority shall, after the case of an animal bite is reported, determine whether the animal shall be immediately destroyed and its head submitted to one of the State or county diagnostic laboratories for a rabies examination or whether some other action shall be pursued.

(2) Notwithstanding paragraph (1), when a healthy dog or cat bites or otherwise potentially exposes a human to rabies, the dog or cat shall be quarantined in a place and

manner approved by the Department or the local health officer for 10 days after the date of the bite, unless the Department or local health officer directs otherwise.

(3) If a quarantine is imposed, the Department or the local health officer may order the owner or custodian of a biting animal to have the animal examined for symptoms of rabies during the quarantine period by a veterinarian licensed by the State Board of Veterinary Medicine. The cost of the examinations and other associated costs shall be borne by the owner or custodian of the biting animal.

**§ 27.163. Special requirements for psittacosis.**

A quarantine is not required for household contacts of a bird that is a carrier of psittacosis. However, parts of any buildings that housed birds infected with psittacosis may not be used by human beings until thoroughly cleaned and disinfected.

**§ 27.164. Special requirements for close contacts of cases of plague, pharyngitis or pneumonia.**

A close contact of any person or animal that is diagnosed as having plague (Yersinia pestis) pharyngitis, or pneumonia shall be provided chemoprophylaxis and placed under surveillance for 7 days.

## Subchapter F. MISCELLANEOUS PROVISIONS

### PSITTACOSIS

**§ 27.181. Records of the sale, purchase or exchange of psittacine birds.**

A dealer who purchases, sells, exchanges or gives away a bird of the psittacine family shall keep a record for 2 years of each transaction. This record shall include the number of birds purchased, sold, exchanged or given away, the date of the transaction, and the name and address of the person from whom purchased, to whom sold or given away, or with whom exchanged. Records shall be available for official inspection.

**§ 27.183. Occurrence of psittacosis.**

(a) The occurrence of a case of psittacosis in the human or avian family shall be cause for the LMRO to make an epidemiologic investigation to determine the source of infection.

(b) Psittacine birds or other birds found on the same premises with a case of human or avian psittacosis shall be quarantined and treated, or destroyed, as prescribed by the Department or local health authority. Aviaries, pet shops or other sources from which the birds were procured shall be quarantined until the quarantine is terminated by the Department or local health authority. If quarantine is not maintained, the Department or local health authority may seize and destroy the birds for which quarantine was ordered. The Department or local health authority shall destroy the bodies of the birds in a manner which will preclude, insofar as possible, the dissemination of the suspected infecting organism.

(c) A bird with psittacosis that has been placed under quarantine may not be sold or removed from isolation until it has been treated for at least 7 days. After 7 days, the bird may be sold, but the seller shall make the buyer aware in writing of the significance of psittacosis and the signs and symptoms for which to look. The signed receipt shall include a copy of any documents provided to the new owner, and shall be maintained at the place of sale for 6 months after the sale of the quarantined bird. The duration of additional treatment necessary shall be established at the time of sale and the seller shall inform the new owner of the duration of the additional treatment. The seller shall supply the new owner with a supply of medicated feed sufficient for the duration of the treatment.

**§ 27.184. (Reserved).**

### IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS

**§ 27.191. Importation of animals and animal products during a public health emergency.**

In the event of a public health emergency, the Department may direct the following procedures for the importation of animals or animal products:

(1) *Permit required.* The Department may designate a specific type of animal or animal product which may not be brought or transported into this Commonwealth unless that animal or animal product is accompanied by a permit issued by the Department or other agency authorized by the Department to issue permits.

(2) *Issuance of permits.* A permit will be issued upon request if the source of the animal or animal product is established to the satisfaction of the Department or its agent and that source is known to be free of infection.

(3) *Destruction of animals and animal products.* If the animal or animal product is not accompanied by a permit or if the source is not the same as that set forth in the permit, the animal or animal product shall be immediately seized and destroyed and the means of conveyance disinfected at the expense of the owner.

**§ 27.192. Importation and sale of live turtles.**

A live turtle may not be sold or distributed or offered for sale or distribution within this Commonwealth except when the seller or distributor of the turtles shall warrant to the satisfaction of the Department that the shipment of turtles is free from salmonella contamination. The Department may waive the requirements of this section for live turtles sold or distributed within this Commonwealth for the purposes of research, other zoological purposes or for food.

### DISPOSITION OF EFFECTS AND REMAINS OF INFECTED PERSONS

**§ 27.201. Disposition of articles exposed to contamination.**

A person may not give, lend, sell, transmit or expose, without previous cleaning and a certificate from the Department or local health authority attesting to the cleaning of bedding, clothing, rags or other articles which have been exposed to contamination from bubonic plague, smallpox (variola, varioloid) or anthrax, except when the transmission of the articles is made with proper precaution and with the permission of the Department or local health authority for the purpose of having them cleaned.

**§ 27.202. Lease of premises occupied by a person with a communicable disease.**

A person may not rent a room, house or part of a house in which there has been a person suffering from a communicable disease to another person without having the room, house or part of a house and articles therein previously cleaned to the satisfaction of the Department or local health authority prior to occupancy. The keeping of a hotel, boarding house or an apartment house shall be deemed as renting part of a house to a person who shall be admitted as a guest into the hotel, boarding house or apartment house.

**§ 27.204. Funeral services.**

Services held in connection with the funeral of a person who has died with a disease for which isolation or quarantine is required, shall be private when so ordered by the Department or local health authority having jurisdiction in the area in which the services shall be held. When the local health authority is not an LMRO, the local health authority shall consult with and receive the approval of the Department prior to making the order. The attendance at private funerals shall include only the immediate relatives of the deceased and the necessary number of pallbearers.

**§ 27.205. (Reserved).**

## PART IV. HEALTH FACILITIES

## Subpart C. LONG-TERM CARE FACILITIES

## CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

**§ 211.1. Reportable diseases.**

(a) When a resident develops a reportable disease, the administrator shall report the information to the appropriate health agencies and appropriate Division of Nursing Care Facilities field office. Reportable diseases, infections and conditions are listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities).

(b) Cases of scabies and lice shall be reported to the appropriate Division of Nursing Care Facilities field office.

(c) Significant nosocomial outbreaks, as determined by the facility's medical director, Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin-Resistant Staphylococcus Aureus (VRSA), Vancomycin-Resistant Enterocci (VRE) and Vancomycin-Resistant Stapylococcus Epidermidis (VRSE) shall be reported to the appropriate Division of Nursing Care Facilities field office.

[Pa.B. Doc. No. 02-161. Filed for public inspection January 25, 2002, 9:00 a.m.]

# NOTICES

## DEPARTMENT OF HEALTH

### Immunization Practices for Children in Child Care Group Settings

In accordance with 28 Pa. Code § 27.77(c) (relating to immunization requirements for children in child care group settings), the Department of Health (Department) is publishing a list of Morbidity and Mortality Weekly Report (MMWR) publications that contain the Advisory Committee on Immunization Practices (ACIP) recommendations that meet the standards of 28 Pa. Code § 27.77(c). Children in child care group settings as defined by 28 Pa. Code § 27.77(c) are required to be immunized in accordance with the recommendations included in the following publications:

"General Recommendations on Immunizations," MMWR, January 28, 1994/Vol. 43/No. RR-1, pages 1-38.

"Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures," MMWR, August 8, 1991/Vol. 40/No. RR-10, pages 1-28, with the exception of materials relating to Diphtheria Antitoxin.

"Haemophilus b Conjugate Vaccines for Prevention of Haemophilus influenzae type b Disease Among Infants and Children Two Months of Age and Older," MMWR, January 11, 1991/Vol. 40/No. RR-1, pages 1-7.

"Recommendations for the use of Haemophilus b Conjugate Vaccines and a Combined Diphtheria, Tetanus, Pertussis, and Haemophilus b Vaccine," MMWR, September 17, 1993/Vol. 42/No. RR-13, pages 1-15.

"Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination," MMWR, November 22, 1991/Vol. 40/No. RR-13, pages 1-25.

"Protection Against Viral Hepatitis," MMWR, February 9, 1990/Vol. 39/No. RR-2, pages 1-21.

"Prevention of Varicella," MMWR, July 12, 1996/Vol. 45/No. RR-11, pages 1-25.

"Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Very Small Children," MMWR, March 28, 1997/Vol. 46/No. RR-7.

"Prevention of Pneumococcal Disease," MMWR, April 4, 1997/Vol. 46/No. RR-8.

"Measles, Mumps, and Rubella—Vaccine Use and Strategies for Elimination of Measles, Mumps, and Rubella, and Congenital Rubella Syndrome and Control of Mumps," MMWR, May 22, 1998/Vol. 47/No. RR-8.

"Prevention of Varicella Updated," MMWR, May 28, 1999/Vol. 48/No. RR-6.

"Prevention of Hepatitis A Through Active or Passive Immunization," MMWR, October 1, 1999/Vol. 48/No. RR-12.

"Poliomyelitis Prevention in the United States," MMWR, May 19, 2000/Vol. 49/No. RR-5.

"Preventing Pneumococcal Disease Among Infants and Young Children," MMWR, October 6, 2000/Vol. 49/No. RR-9.

"Use of Diphtheria Toxoid-Tetanus Toxiod-Acellular Pertussis Vaccine as a Five-Dose Series," MMWR, November 17, 2000/Vol. 39/No. 13.

"Prevention and Control of Influenza," MMWR, April 20, 2001/Vol. 50/No. RR-4.

Persons with a disability who require an alternative format of this notice (for example, large print, audiotape, Braille), should contact Alice Gray, Director, Division of Immunization, Department of Health, P. O. Box 90, Harrisburg, PA 17108-0090, (717) 787-5681 or at V/TT: (717) 783-6154 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800) 654-5984 [TT].

ROBERT S. ZIMMERMAN, Jr.,
*Secretary*

(*Editor's Note*: For the text of a final-form rulemaking relating to this notice, see 32 Pa.B. 491 (January 26, 2002).)

[Pa.B. Doc. No. 02-162. Filed for public inspection January 25, 2002, 9:00 a.m.]