DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
4200 Health Promotion and Disease Prevention

4202 Control of Communicable and Other Disease Conditions

1.0 Definitions

The following words and terms, when used in this regulation, have the following meaning:

"**Case**" means a person whose body has been invaded by an infectious agent with the result that clinical symptoms have occurred.

"**CDC**" means the Centers for Disease Control and Prevention an agency of the United States Department of Health and Human Services that works to protect public health and safety by providing information to enhance health decisions and promoting health through partnerships with state health departments and other organizations. The CDC is dedicated to protecting health and promoting quality of life through the prevention and control of disease, injury, and disability. As the national public health agency for the United States, the CDC is committed to programs that reduce the health and economic consequences of leading causes of death and disability, thereby ensuring a long, productive, healthy life for all people. The CDC provides the standard national measures for healthcare-associated infections as well as analytic tools that enable each facility to assess its progress and identify where additional prevention or response efforts are needed.

"**Child care facility**" means any organization or business created for, and having as its major purpose, the daily care or education of children under the age of 7 years.

"**Communicable disease**" see "Contagious disease".

"**Contact**" means a person or animal that has been in such association with an infected person or animal or a contaminated environment as to have had exposure to the infection.

"**Contagious disease**" means an infectious disease that can be transmitted from person to person, or animal to person.

"**Designee**" means the person named by the Director of the Division of Public Health to assume a specific responsibility.

"**Division**" or "**DPH**" means the Delaware Division of Public Health.

"**Division Director**" means the Director of the Division of Public Health.

"**Directly observed therapy**" or "**DOT**" means an adherence-enhancing strategy in which a health care worker or other designated person observes the patient to ensure each dose of medication is swallowed.

"**DPHL**" means the Division of Public Health Laboratory.

"**Epidemic**" means the occurrence in persons in a community, institution, region, or other defined area of cases of an illness of similar nature clearly in excess of normal expectancy.

"**Health care provider**" means any person or entity who provides health care services, including hospitals, medical clinics and offices, special care facilities, medical laboratories, physicians, pharmacists, dentists, physician assistants, nurse practitioners, registered and other nurses, paramedics, emergency medical or laboratory technicians, and ambulance and emergency medical workers.

"**Human immunodeficiency virus**" or "**HIV**" means the presence of repeatedly reactive screening tests for HIV antibody in accord with the CDC case definition of HIV and DPHL endorsed diagnostic protocols.

"**Infectious disease**" means a disease caused by a living organism or other pathogen, including a fungus, bacillus, parasite, protozoan, or virus. An infectious disease may or may not be transmissible from person to person or animal to person.

"**Isolation**" means the physical separation and confinement of an individual or group of individuals who are infected or reasonably believed to be infected with a contagious or possibly contagious disease from non-isolated individuals to prevent or limit the transmission of the disease.

"**Medical Examiner**" means a physician appointed pursuant to 29 **Del.C.** §4703 or §7903(a)(3) who is authorized to investigate the causes and circumstances of death.

"**Nosocomial disease**" or "**healthcare-associated infection**" means a disease occurring in a patient in a healthcare facility and in whom it was not present or incubating at the time of admission.

"**Notification**" means a written, electronic, or verbal report as required by any section of this regulation.

"**Outbreak**" - see "**Epidemic**".

"**Public health emergency**" is an occurrence or imminent threat of an illness or health condition that is believed to be caused by any of the following:

1. Bioterrorism;
2. The appearance of a novel or previously controlled or eradicated infectious agent or biological toxin; or
3. A chemical attack or accidental release;

And, which poses a high probability of any of the following harms:

1. Many deaths in the affected populations;
2. Many serious or long-term disabilities in the affected population; or
3. Widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to many people in the affected population.

"**Quarantine**" means the physical separation and confinement of an individual or group of individuals who are or may have been exposed to a contagious or possibly contagious disease but who do not yet show signs or symptoms of the contagious disease from non-quarantined individuals to prevent or limit the transmission of the disease.

"**Reportable disease**" means an infectious disease or condition of public health significance required to be reported to the Division of Public Health in accordance with this regulation. A subset of reportable diseases is shared with the CDC and referred to as national notifiable conditions.

"**Resistant organism**" or "**drug-resistant organism**" means any organism which traditionally was inactivated or killed by a drug but has, over time, developed mechanisms to render that drug ineffective.

"**Sensitive situation**" means a setting, as determined by the Director of the Division of Public Health or designee, in which the presence of a person or animal infected with or suspected of being infected with a reportable or other communicable disease or condition which may affect the public health would increase significantly the probability of spread of such disease and would, therefore, constitute a public health hazard, but not a public health emergency as defined in 20 **Del.C.** §3132(11). Sensitive situations may include schools, child care facilities, hospitals, and other patient-care facilities, food storage, food processing establishments or food outlets.

"**Source of infection**" means the person, animal, object, or substance from which an infectious agent passes directly to the host.

"**Suspect**" means a person or animal whose medical history and symptoms suggest that the person or animal may have or may be developing an infectious disease condition.

"**Syndromic surveillance**" means surveillance using signs and symptoms that precede diagnosis and may signal a sufficient probability of a case or an outbreak to warrant further public health response.

9 DE Reg. 1188 (02/01/06)
17 DE Reg. 320 (09/01/13)
23 DE Reg. 665 (02/01/20)
24 DE Reg. 791 (02/01/21)
27 DE Reg. 863 (05/01/24)

2.0 Conditions to be Reported, Timeliness and Manner of Reporting

2.1 Reportable Diseases Reporting

2.1.1 The reportable diseases specified in the Appendices to this regulation are declared as dangerous to the public health. The occurrence or suspected occurrence of these diseases, including those identified after death, shall be reported as defined in Section 3.0 to the Division of Public Health.

2.1.2 The Division of Public Health may list additional diseases and conditions on its reporting forms for which reporting is encouraged but not required.

2.2 Timeliness and Content of Reportable Disease Reports

2.2.1 Reports pursuant to this subsection shall be made electronically, by telephone, by facsimile (fax), or in writing within 48 hours of recognition to the Division Director or designee, except as otherwise noted in this regulation or specified in the Appendices to this regulation.

2.2.2 Except as otherwise provided by this regulation, reports of reportable or other diseases or conditions required to be reported by this regulation shall contain sufficient information to contact the person

reporting. The following information shall be reported: the name, address, telephone number, date of birth, race, ethnicity, gender, and disease of the person ill or infected, the date of onset of illness; the name, address, and telephone number of the person's health care provider; and any pertinent laboratory information.

2.3 Ordinary Skill

2.3.1 Any person who is required to report a disease or other condition under this section shall use ordinary skill in determining the presence of the reportable disease or condition.

2.3.2 If the determination of the disease or condition is disputable and the disease or condition may have potential public health concern or may potentially be an indicator of a public health emergency, the Division Director or designee may request tests through the Division's laboratory or another certified laboratory to help resolve uncertainty.

2.4 Privacy Protection

2.4.1 The Division of Public Health is the state's recognized public health authority as defined in HIPAA (45 CFR § 164.501) pursuant to 45 CFR § 164.512 (b).

2.4.2 Covered entities may disclose without individual authorization, protected health information to public health authorities.

2.4.3 As the recognized public health authority for the State of Delaware, the Division of Public Health is authorized by law to collect or receive protected health information for the purpose of preventing or controlling disease, injury or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions.

2.4.4 The information required to be reported represents the minimum necessary to carry out our public health mandates pursuant to 45 CFR § 164.514(d) of the HIPAA Privacy Rule.

2.5 Electronic Reporting Systems

2.5.1 The Division may establish a system for electronic reporting to improve the accuracy and timeliness of reporting diseases defined by state law as reportable. The system shall be technologically designed to ensure data security and compatibility with other state and federal public health reporting systems to the extent feasible.

2.5.2 Those authorized to participate in electronic reporting systems must meet minimum standards for compliance and training as determined by the Division.

2.6 Syndromic Surveillance Reporting

2.6.1 The Division may establish a statewide syndromic surveillance system. The system shall be technologically designed to ensure data security and compatibility with other state and federal public health reporting systems to the extent feasible.

2.6.2 Those authorized to participate in syndromic surveillance must meet minimum standards for compliance and training as determined by the Division. In addition, syndromic surveillance data shall include the patient's name, address, date of birth, race, ethnicity, and gender.

2.6.3 The Director will establish what syndromes will be reported. The Director may change or add reportable syndromes to assure the monitoring of health events of public health importance.

9 DE Reg. 1188 (02/01/06)
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3.0 Report of Outbreaks and Potential Causes of a Public Health Emergency

3.1 Outbreaks. Any health care provider, having knowledge of any outbreak of any reportable disease, cluster of any illness which may be of public concern, or any unusual group expression or individual case of a disease of public concern as determined by the Division Director, is required to report such occurrences within 24 hours to the Division Director or designee.

3.2 Public Health Emergencies

3.2.1 A health care provider or any other person having knowledge of a public health emergency shall immediately report all cases of persons who harbor any illness or health condition, or symptoms of said illness or health condition, that may be potential causes of a public health emergency. The Division Director or designee may declare certain illnesses or health conditions as public health emergencies, which shall be reported.

3.2.2 A pharmacist shall report any unusual or increased prescription rates, unusual types of prescriptions, or unusual trends in pharmacy visits that may be potential causes of a public health emergency. Prescription-related events that require a report include:

3.2.2.1 An unusual increase in the number of prescriptions to treat fever, respiratory or gastrointestinal complaints;

3.2.2.2 An unusual increase in the number of prescriptions for antibiotics or other pharmaceuticals or sales of over-the-counter pharmaceuticals; and

3.2.2.3 Any prescription that treats a disease that is relatively uncommon or may be associated with terrorism.

9 DE Reg. 1188 (02/01/06)

23 DE Reg. 665 (02/01/20)

27 DE Reg. 863 (05/01/24)

4.0 Persons and Institutions Required to Report

4.1 Health Care Providers

4.1.1 Reports required by Sections 2.0 and 3.0 shall be made to the Division Director or designee by the following:

4.1.1.1 Any health care provider who diagnoses or suspects the existence of any disease required to be reported; or

4.1.1.2 The medical examiner in such cases that the medical examiner examines.

4.2 Hospitals

4.2.1 The chief administrative officer of each civilian hospital, long-term care facility, or other patient-care facility shall (and the United States military and Veterans Administration Hospitals are requested to) appoint an individual from the staff, hereinafter referred to as "reporting officer," who shall be responsible for reporting cases or suspect cases of diseases on the reportable disease list in persons admitted to, attended to, or residing in the facility.

4.2.2 Reporting of a case or suspect case of a reportable disease by a hospital fulfills the requirements of the health care provider to report; however, it is the responsibility of the attending practitioner to ensure that the report is made pursuant to subsection 4.1.

4.2.3 The hospital reporting officer shall also report to the Division Director or designee communicable diseases not specified in Section 2.0, should the disease occur in a nosocomial disease outbreak situation that may significantly impact the public health. Such reports shall be made within 24 hours of the recognition of such a situation.

4.2.4 Hospitals shall make a good effort to meet the technologic standards provided by the Division to report reportable diseases electronically per subsection 2.5 and syndromic surveillance data per subsection 2.6. Hospitals meeting said standards shall use this method of reporting.

4.3 Laboratories

4.3.1 Any person in charge of a clinical or hospital laboratory or other facilities in which a laboratory examination of any specimen derived from a human body and submitted for examination shall share with the DPHL specimens or culture results for agents causing certain diseases listed in the Appendices of this regulation. In addition, such laboratories shall report to the Division of Public Health results of laboratory examinations of specimens indicating or suggesting the existence of:

4.3.1.1 A reportable disease;

4.3.1.2 A suspected agent of bioterrorism immediately upon receipt of the results; or

4.3.1.3 Any other potential agent or specimen that may be the cause of an outbreak or public health emergency immediately upon receipt of the results.

4.3.2 The Director or designee may contact the patient or the potential contacts so identified from laboratory reports only after consulting with the attending practitioner, when the practitioner is known and when said consultation will not delay the timely control of a communicable disease.

4.3.3 Reporting of antibiotic resistant organisms

4.3.3.1 Any person in charge of a clinical or hospital laboratory, or other facility in which a laboratory examination of any specimen derived from a human body and submitted for microbiologic examination yields a non-susceptible species of microorganism identified in Appendix I by (A), will report the infected person's name, address, date of birth, race, ethnicity, sex, site of isolation, date of isolation and Minimum Inhibitory Concentration and Zone of Inhibition (MIC/Zone) diameter to the Division of Public Health.

4.3.3.2 Upon request, the Division may waive the requirement for the reporting of said demographic information until such time that electronic reporting facilitates its reporting.

4.3.3.3 The number of susceptible and non-susceptible isolates of any of these organisms shall be reported monthly to the Division of Public Health.

4.3.4 Laboratories authorized to report reportable diseases electronically per subsection 2.5, shall use this method of reporting.

4.4 Others

4.4.1 In addition to those who are required to report reportable diseases, the following individuals are requested and authorized to notify the Division Director or designee of the name and address of any person in the individual's family, care, employ, class, jurisdiction, or custody of control, who is suspected of being afflicted with a reportable disease although no health care provider, as in subsection 4.1 of this regulation, has been consulted:

4.4.1.1 Every parent, guardian, householder;

4.4.1.2 Every midwife;

4.4.1.3 Every superintendent, principal, teacher, or counselor of a public or private school;

4.4.1.4 Every administrator of a public or private institution of higher learning;

4.4.1.5 Every owner, operator, or teacher of a child care facility;

4.4.1.6 Every owner or manager of a dairy, restaurant, or food storage, food-processing establishment, or food outlet;

4.4.1.7 Every superintendent or manager of a public or private camp, home, or institution; and

4.4.1.8 Every director or supervisor of a military installation, military or Veterans Administration hospital, prison, or juvenile detention center.

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5.0 Investigation of Case

5.1 Action to Be Taken

5.1.1 Upon being notified of a case or suspected case of a reportable disease or an outbreak of a reportable disease or other disease condition in persons or animals, the Director of the Division or designee may act as permitted in this regulation, and additionally as deemed necessary to protect the public health.

5.1.2 If the nature of the disease and the circumstances warrant, the Director of the Division or designee may make or cause to be made an examination of the patient to verify the diagnosis, make an investigation to determine the source of infection, and take other appropriate action to prevent or control the spread of the disease. These actions may include:

5.1.2.1 Confinement on a temporary basis until the patient is no longer infectious; and

5.1.2.2 Obligatory medical treatment in order to prevent the spread of disease in the community.

5.2 Examination of Patient

5.2.1 Any person suspected of being afflicted with any reportable disease shall be subject to physical examination and inspection by any designated representative of the Division of Public Health, except that a duly authorized warrant or court order shall be presented to show just cause in instances where the suspect refuses such examination and inspection.

5.2.2 Such examination shall include the submission of bodily specimens when deemed necessary by the Division Director or designee.

5.3 Sensitive Situations

5.3.1 No person known to be infected with a contagious disease or suspected of being infected with a contagious disease shall engage in sensitive situations as defined in Section 1.0 of this regulation until judged by the Division Director or designee to be either free of such disease or no longer a threat to public health. Such action shall be in accord with accepted public health practice and reasonably calculated to abate the potential public health risk.

5.3.2 When, pursuant to subsection 5.3.1, it is necessary to require that a person not engage in a sensitive situation because that person is infected or suspected of being infected with a contagious disease, the Division Director or designee shall provide, in writing, instructions specifying the nature of the restrictions and conditions necessary to terminate the restrictions.

5.3.2.1 These written instructions shall be provided to the person infected or suspected of being infected with a contagious disease and to that person's employer or other such individual responsible for the sensitive situation.

5.3.3 The Division Director or designee shall have the authority to exclude from attendance in a child care facility any child or employee suspected of being infected with a contagious disease that, in the opinion of the Division Director or designee, significantly threatens the public health. In addition, no person shall attend or be employed in a child care facility who has the following symptoms:

5.3.3.1 Diarrhea, severe coughing, difficult or rapid breathing, yellowish skin or eyes, pinkeye, or an untreated louse or scabies infestation;

5.3.3.2 Fever (100°F by oral thermometer or 101°F by rectal thermometer or higher) accompanied by 1 of the following: unusual spots or rashes, sore throat or trouble swallowing, infected skin patches, unusually dark tea-colored urine, gray or white stool, headache and stiff neck, vomiting, unusually cranky behavior, or loss of appetite.

5.3.3.3 Any other symptoms that, in the opinion of the Division Director or designee, suggest the presence of a contagious disease that significantly threatens the public health. Exclusion from a child care facility in this case shall be effective upon written notification pursuant to subsection 5.3.2.

9 DE Reg. 1188 (02/01/06)
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6.0 Quarantine and Isolation

6.1 The Division's authority may exercise the following over persons:

6.1.1 To establish and maintain places of isolation and quarantine;

6.1.2 To isolate and quarantine individuals subject to the procedures enumerated in this section; and

6.1.3 To require isolation or quarantine of any person by the least restrictive means necessary to protect the public health, subject to the other provisions of this section. All reasonable means shall be taken to prevent the transmission of infection among the isolated or quarantined individuals.

6.2 Standard for quarantine or isolation

6.2.1 Persons shall be isolated or quarantined if it is determined by clear and convincing evidence that the person to be isolated or quarantined poses a significant risk of transmitting a disease to others with serious consequences. A person's refusal to accept medical examination, vaccination or treatment shall constitute prima facie evidence that said person should be quarantined or isolated.

6.2.2 Isolation or quarantine of any person shall be terminated when such person no longer poses a significant risk of transmitting a disease to others with serious consequences.

6.3 Character of isolation and quarantine area

6.3.1 To the extent possible, the premises in which persons are isolated or quarantined shall be maintained in safe and hygienic manners designed to minimize the likelihood of further transmission of infection or other harm to persons subject to isolation or quarantine. Adequate food, clothing, medication and other necessities and competent medical care shall be provided.

6.3.2 Isolated individuals must be confined separately from quarantined individuals.

6.3.3 The health status of isolated and quarantined individuals must be monitored regularly to determine if their status should change. If a quarantined individual subsequently becomes infected or is reasonably believed to have become infected with a contagious or possibly contagious disease, the individual must promptly be moved to isolation.

6.4 Transportation

6.4.1 Transportation or removal of quarantined or isolated persons may be made only with prior approval of the Division Director or designee.

6.4.2 Transportation or removal of quarantined or isolated persons shall be made in accordance with orders issued by the Division Director or designee. Quarantine or isolation shall be resumed immediately upon arrival of quarantined or isolated person at point of destination for a time period in accord with accepted public health practices.

6.5 Disinfection

6.5.1 Concurrent disinfection is required of infectious or potentially infectious secretions or excretions of any quarantined or isolated person or animal or of objects contaminated by such secretions or excretions. The collection, storage, and disposal of such contaminated matter and disinfection procedures shall be approved by the Division Director or designee.

6.5.2 Disinfection shall also be carried out at the termination of the period of quarantine or isolation and shall be applied to the quarter vacated. The disinfection procedures shall be as approved by the Division Director or designee.

6.6 Control of quarantine and isolation area

6.6.1 A person subject to isolation or quarantine shall obey the Division's rules and orders, shall not go beyond the isolation or quarantine premises, and shall not put themselves in contact with any person not subject to isolation or quarantine other than a physician or other health care provider, public health authority, or person authorized to enter isolation or quarantine premises by the Division's authority. Any person entering isolation or quarantine premises may be isolated or quarantined.

6.6.2 No person, other than a person authorized by the Division, shall enter isolation or quarantine premises. If by reason of an unauthorized entry into an isolation or quarantine premises, the person poses a danger to public health, that person may be subject to isolation or quarantine pursuant to the provisions of this section.

6.7 Procedures for isolation and quarantine. The following procedures shall protect the due process rights of individuals:

6.7.1 The Division shall petition the Superior Court for an order authorizing the isolation or quarantine of an individual or groups of individuals. Said petition shall specify the following:

6.7.1.1 The identity of the individual or group of individuals subject to isolation or quarantine;

6.7.1.2 The premises subject to isolation or quarantine;

6.7.1.3 The date and time at which the Division requests isolation or quarantine to commence;

6.7.1.4 The suspected contagious disease, if known;

6.7.1.5 A statement of compliance with the conditions and principles for isolation and quarantine;

6.7.1.6 A statement of the basis upon which isolation or quarantine is justified; and

6.7.1.7 A statement of what effort, if any, has been made to give notice of the hearing to the individual or group of individuals to be isolated or quarantined, or the reason supporting the claim that notice should not be required.

6.7.2 Ex parte orders

6.7.2.1 Before isolating or quarantining a person, the Division shall obtain a written order, which may be an ex parte order, from the Superior Court authorizing such action. An order, which may be an ex parte order, shall be requested as part of a petition filed in compliance with subsections 6.1 through 6.2.

6.7.2.2 The Court shall grant an order, which may be an ex parte order, upon finding by clear and convincing evidence that isolation or quarantine is warranted pursuant to the provisions of Section 6.0 of this regulation.

6.7.2.3 A copy of the authorizing order shall be given to the person ordered to be isolated or quarantined, along with notification that the person has a right to a hearing under subsection 6.7.

6.7.3 Temporary quarantine or isolation pending filing of a petition

6.7.3.1 Notwithstanding the preceding subsections, the Division may isolate or quarantine a person without first obtaining a written order, which may be an ex parte order, from the Court if a physician determines that any delay in the isolation or quarantine of the person would pose an immediate and severe danger to the public health.

6.7.3.2 Following such isolation or quarantine, the Division shall file a petition within 24 hours.

6.7.3.3 If the Division exercises its powers, it must provide a written directive to the individuals or groups under temporary quarantine or isolation indicating the identities of the individuals or groups subject to the directive, the premises subject to isolation or quarantine, the date and time that the directive commences, and the suspected contagious disease (if known).

6.7.4 Speedy hearing. The Court shall grant a hearing within 72 hours of the filing of a petition when an individual has been isolated or quarantined.

6.7.5 Consolidation of claims. The Court may order consolidation of individual claims into a group of claims where:

6.7.5.1 The number of individuals involved or to be affected is so large as to render individual participation impractical;

6.7.5.2 There are questions of law or fact common to the individual claims or rights to be determined;

6.7.5.3 The group claims or rights to be determined are typical of the affected individuals' claims or rights; and

6.7.5.4 The entire group will be adequately represented in the consolidation, giving due regard to the rights of affected individuals.

6.8 Relief for isolated and quarantined persons

6.8.1 On or after 10 days following a hearing, a person isolated or quarantined pursuant to the provisions of this section may request in writing a Court hearing to contest the person’s continued isolation or quarantine.

6.8.1.1 The hearing shall be held within 72 hours of receipt of such request, excluding Saturdays, Sundays, and legal holidays.

6.8.1.2 A request for a hearing shall not alter the order of isolation or quarantine.

6.8.1.3 At the hearing, the Division must show by clear and convincing evidence that continuation of the isolation or quarantine is warranted because the person poses a significant risk of transmitting a disease to others with serious consequences.

6.8.2 A person isolated or quarantined pursuant to the provisions of this section may request a hearing in the Superior Court for remedies regarding the person’s treatment and the terms and conditions of such quarantine or isolation.

6.8.2.1 Upon receiving a request for either type of hearing, the Court shall fix a date for a hearing. The hearing shall take place within 10 days of the receipt of the request by the Court.

6.8.2.2 The request for a hearing shall not alter the order of isolation or quarantine.

6.8.3 If upon a hearing, the Court finds that the isolation or quarantine of the individual is not warranted under the provisions of this section, then the person shall be immediately released from isolation or quarantine. If the Court finds that the isolation or quarantine of the individual is not in compliance with the provisions of this section, the Court may then fashion remedies appropriate to the circumstances of the necessity for the isolation or quarantine and in keeping with the provisions of this section.

6.8.4 No person shall be permanently terminated from employment by a Delaware employer as a result of being isolated or quarantined pursuant to this section. However, this paragraph shall not apply to a person who has been quarantined as a result of refusing to comply with an examination, treatment, or vaccination program, nor shall it apply to a person whose conduct caused the necessity for the isolation or quarantine.

6.9 Additional due process protections

6.9.1 A record of proceedings before the Court shall be made and retained for at least 3 years.

6.9.2 The petitioner shall have the right to be represented by counsel or other lawful representative, and the State shall provide counsel to indigent persons against whom proceedings are initiated pursuant to this section.

6.9.3 The manner in which the request for a hearing is filed and acted upon will be in accordance with the existing laws and rules of the Superior Court or any such rules that are developed by the Court, provided that hearings should be held by any means that will allow all necessary persons to participate in the event that a public health emergency makes personal appearances impractical.

6.10 The provisions of this section are subject to the provisions of 16 **Del.C.** §§520-532. Provisions of 16 **Del.C.** §§520-532 that conflict with provisions of this section take precedence over this section.

9 DE Reg. 1188 (02/01/06)
22 DE Reg. 1012 (06/01/19)
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7.0 Control of Specific Contagious Diseases

7.1 Vaccine Preventable Diseases

7.1.1 All preschool children who are enrolled in a child care facility must be age-appropriately vaccinated against diseases prescribed by the Division Director.

7.1.1.1 For those diseases so prescribed, the most current recommendations of the federal Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) shall determine the vaccines and vaccination schedules acceptable for compliance with this regulation.

7.1.2 Any child entering private school must be age-appropriately vaccinated against diseases prescribed by the Division Director, prior to enrolling in school.

7.1.2.1 For those diseases so prescribed, the most current recommendations of the federal Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) shall determine the vaccines and vaccination schedules acceptable for compliance with this regulation.

7.1.2.2 This provision pertains to all children between the ages of 2 months and 21 years entering or being admitted to a Delaware private school for the first time including foreign exchange students, immigrants, students from other states and territories and children entering from public schools.

7.1.3 Acceptable documentation of the receipt of immunization as required by subsections 7.1.1 and 7.1.2 shall include either a medical record signed by a physician, or a valid immunization record issued by the State of Delaware or another State, which specifies the vaccine given and the date of administration.

7.1.4 Immunization requirements pursuant to subsections 7.1.1 and 7.1.2 shall be waived for:

7.1.4.1 Children whose physicians have submitted, in writing, that a specific immunizing agent would be detrimental to that child; and

7.1.4.2 Children whose parents or guardians present a notarized document that immunization is against their religious beliefs.

7.1.5 Child care facilities and private schools (grades K-12) shall maintain on file an immunization record for each child. The facility will also be responsible to report to the Division Director or designee on an annual basis the immunization status of its enrollees.

7.1.6 Parents whose children present immunization records which show that immunizations are lacking will be allowed 14 days (or such time as may be appropriate for a particular vaccination) to complete the required age-appropriate doses of vaccine for their children.

7.1.6.1 In instances where more than 14 days will be necessary to complete the age-appropriate immunization schedule, an extension may be allowed in order to obtain the required immunizations. Extension of the 14-day allowance because of missed appointments to receive needed immunizations shall not be permitted.

7.1.7 When a child's records are lost and the parent states that the child has completed the child’s series of immunizations, or a child has been refused admission or continued attendance at a child care facility or private school for lack of acceptable evidence of immunization as specified in this regulation, a written certification must be provided by a health care provider who has administered the necessary age-appropriate immunizations to the child according to the current ACIP immunization schedule.

7.1.8 It is the responsibility of the child care facility or private school to exclude a child prior to admission or from continued attendance who has failed to document required immunizations pursuant to this section.

7.1.9 Upon the occurrence of a case or suspect case of 1 of the vaccine preventable diseases specified in pursuant to subsections 7.1.1 and 7.1.2, any child not immunized against that disease shall be excluded from the premises until the Division Director or designee has determined that the disease risk to the unimmunized child has passed.

7.1.9.1 Such exclusion shall apply to all those in the facility who are admitted under either medical or religious exemption as well as to those previously admitted who have not yet received vaccine against the disease which has occurred.

7.1.9.2 If, in the judgment of the Division Director or designee, the continued operation of the facility presents a risk of the spread of disease to the public at large, the Division Director or designee shall have the authority to close the facility until the risk of disease occurrence has passed.

7.1.10 All full-time students of post-secondary educational institutions (including post-high school institutions of education/training, such as universities, private colleges, technical and community colleges, vocational technical schools, and hospital nursing schools) and all full and part-time students in such educational institutions if engaged in patient-care related curriculums (including nursing, dentistry, and medical laboratory technology), shall be required to show evidence of immunity to measles, rubella, and mumps prior to enrollment by the following criteria:

7.1.10.1 Measles immunity:

7.1.10.1.1 Persons born before January 1, 1957; or

7.1.10.1.2 Physician documented history of measles disease; or

7.1.10.1.3 Serological confirmation of measles immunity; or

7.1.10.1.4 A documented receipt from a physician or health facility that 2 doses of measles vaccine were administered after 12 months of age.

7.1.10.2 Rubella immunity:

7.1.10.2.1 Persons born before January 1, 1957; except women who could become pregnant; or

7.1.10.2.2 Laboratory evidence of antibodies to rubella virus; or

7.1.10.2.3 A documented receipt from a physician or health facility that rubella vaccine was administered on or after 12 months of age.

7.1.10.3 Mumps immunity:

7.1.10.3.1 Persons born before January 1, 1957; or

7.1.10.3.2 Physician diagnosed history of mumps disease; or

7.1.10.3.3 Laboratory evidence of immunity; or

7.1.10.3.4 A documented receipt from a physician or health facility that mumps vaccine was administered on or after 12 months of age.

7.1.11 Immunization requirements pursuant to subsection 7.1.10 shall be waived for:

7.1.11.1 A student whose licensed physician certifies that such immunization may be detrimental to the student's health;

7.1.11.2 A student who presents a notarized document that immunization is against their religious beliefs.

7.1.12 The student health service, the admissions office, and the office of the university or college registrar are jointly responsible for implementing subsection 7.1.10 through notification of immunization requirements, the collection and verification of documented vaccine histories, identification and notification of students not in compliance, and imposition of sanctions for non-compliance.

7.1.13 Students who cannot show evidence of immunity to measles pursuant to subsection 7.1.10 and who cannot show documented receipt of ever having received measles vaccine shall be permitted to enroll on the condition that 2 doses be administered within 45 days or at the resolution of an existing medical contraindication. Students who cannot show evidence of immunity to rubella or mumps or who have had only 1 dose of measles vaccine shall be permitted to enroll on the condition that measles, mumps, and rubella immunizations be obtained within 14 days or at the resolution of an existing medical contraindication. However, in implementing these requirements, doses of a measles containing vaccine shall not be given closer than 28 days apart.

7.1.14 The Division Director may maintain a registry of the immunization status of persons vaccinated against any vaccine preventable diseases (hereafter called an "immunization registry").

7.1.14.1 Physicians and other health care providers who give immunizations shall report information about the immunization and the person to whom it was given for addition to the immunization registry in a manner prescribed by the Division Director or designee.

7.1.14.2 The Division Director or designee may disclose information from the immunization registry without a patient's, parent's, or guardian's written release authorizing such disclosure to the following:

7.1.14.2.1 The person immunized, or a parent or legal guardian of the person immunized, or persons delegated in writing by same.

7.1.14.2.2 Employees of public agencies or research institutions, however only when it can be shown that the intended use of the information is consistent with the purposes of Section 7.0 of this regulation.

7.1.14.2.3 Health records staff of school districts and child care facilities.

7.1.14.2.4 Persons who are other than public employees who are entrusted with the regular care of those under the care and custody of a state agency including but not limited to operators of day care facilities, group, residential care facilities and adoptive or foster parents.

7.1.14.2.5 Health insurers, however only when the person immunized is a client of the health insurer.

7.1.14.2.6 Health care professionals or their authorized employees who have been given responsibility for the care of the person immunized.

7.1.14.3 If any person authorized in subsection 7.1.14.2 discloses information from the immunization registry for any other purpose, it is an unauthorized release and such person may be subject to civil and criminal penalty.

7.2 Ophthalmia Neonatorum

7.2.1 Any physician, nurse, midwife, or other health care provider so permitted to under the law, who attends the birth of an infant in Delaware, shall provide or cause to be provided prophylactic treatment against inflammation of the eyes of the newborn.

7.2.2 Said prophylactic treatment shall be provided within 1 hour of birth and consist of:

7.2.2.1 1% silver nitrate in single dose containers;

7.2.2.2 A 1-2-centimeter ribbon of sterile ophthalmic ointment containing tetracycline (1%) or erythromycin (0.5%) in single-use tubes; or

7.2.2.3 Other treatment recommended for this purpose as published in the most recent edition of the U.S. Preventive Services Task Force, Guide to Clinical Preventive Services.

7.3 Sexually Transmitted Diseases (STDs)

7.3.1 Appendix I lists STDs regarded to cause significant morbidity and mortality, can be screened, diagnosed and treated, or are of major public health concerns such that surveillance of the disease occurrence is in the public interest, and therefore shall be designated as sexually transmitted and reportable pursuant to 16 **Del.C.** Ch. 7.

7.3.1.1 For the purposes of this section, a suspect is any person having positive or clinical findings of a STD or in whom epidemiologic evidence indicates a STD may exist; or is identified as a sexual contact of a STD case and is provided treatment for the STD on that basis.

7.3.2 Reporting STDs

7.3.2.1 A health care provider who diagnoses, suspects, or treats a reportable STD and every administrator of a health facility or prison in which there is a case of a reportable STD shall report such case to the Division of Public Health.

7.3.2.1.1 Reports provided under this regulation shall specify the infected person's name, address, date of birth, gender, race, and ethnicity as well as the date of onset, name and stage of disease, type and amount of treatment given and the name and address of the submitting licensed health care professional.

7.3.2.2 Any person who oversees a clinical or hospital laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of any specimen derived from a human body yields microscopic, cultural, serological, or other evidence suggestive of a reportable STD shall notify the Division of Public Health.

7.3.2.2.1 Reports provided under this regulation shall specify the name, date of birth, race, ethnicity, gender, and address of the person from whom the specimen was obtained, laboratory findings, and the name and address of the physician and that of the processing clinical

laboratory. Identifying and demographic information shall be required only if made known to the reporting laboratory or hospital in which the laboratory is part.

7.3.2.3 The manner and timing of reports required by subsection 7.3 shall be made in accordance with Section 2.0 of this regulation unless otherwise specified by this regulation.

7.3.2.4 All reports and notification made pursuant to this section are confidential and protected from release except under the provisions of 16 **Del.C.** §§710 and 711.

7.3.2.4.1 From information received from laboratory notifications, the Division of Public Health may contact attending physicians.

7.3.2.4.2 The Division of Public Health shall inform the attending physician, if the notification indicates the person has an attending physician, before contacting a person from whom a specimen was obtained. However, if delays resulting from informing the physician may enhance the spread of the STD, or otherwise endanger the health of either individuals or the public, the Division of Public Health may contact the person without first informing the attending physician.

7.3.2.5 Any person or facility required to report a STD under this section shall permit the Division of Public Health to examine records in order to evaluate compliance with this section.

7.4 Human Immunodeficiency Virus (HIV), Acquired Immunodeficiency Syndrome (AIDS)

7.4.1 HIV/AIDS is regarded to cause significant morbidity and mortality, can be screened, diagnosed and treated, and is of major public health concern, such that surveillance of the disease occurrence is in the public interest, and therefore shall be designated as reportable pursuant to 16 **Del.C.** Ch. 5. Under this provision the following shall be reported:

7.4.1.1 A diagnosis of HIV, according to the Centers for Disease Control and Prevention case definition of HIV.

7.4.1.2 A diagnosis of AIDS, according to the Centers for Disease Control and Prevention case definition of AIDS.

7.4.1.3 A positive confirmed result of any test approved and indicative of the presence of HIV.

7.4.1.4 All CD4 T-lymphocyte percentage and test results and all viral load detection test results (detectable and undetectable).

7.4.1.5 A perinatal exposure of a newborn to HIV.

7.4.2 Reporting of HIV/AIDS and perinatal exposure of newborns to HIV

7.4.2.1 A health care provider who diagnoses or treats HIV/AIDS and every administrator of a health care facility or prison in which there is an HIV/AIDS infected person or perinatal exposure to HIV shall report such information to the Division of Public Health. Reports provided under this subsection shall specify the infected person's name, address, date of birth, gender, mode of transmission, race and ethnicity as well as the date of HIV positive laboratory result, date of perinatal exposure, date of AIDS diagnosis and stage of disease, type and amount of treatment given and the name and address of the submitting health care provider.

7.4.2.2 Any person who oversees a clinical or hospital laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of any specimen derived from a human body yields serological or other evidence of HIV/AIDS, including perinatal exposure to HIV, shall notify the Division of Public Health.

7.4.2.2.1 Reports provided under this subsection shall specify the name, date of birth, race, ethnicity, gender and address of the person from whom the specimen was obtained, laboratory findings, including all CD4 T-lymphocyte percentage test results, all viral load detection test results (detectable and undetectable), and all HIV nucleotide sequencing test results. The name and address of the health care provider and that of the processing clinical laboratory shall also be included.

7.4.2.2.2 Reports made based on an HIV test to detect antibodies shall only be made if confirmed with a Western Blot or other confirmatory test.

7.4.2.2.3 All facilities obtaining blood from human donors for the purpose of transfusion or manufacture of blood products shall report HIV/AIDS consistent with subsection 7.4.2.2.

7.4.2.2.4 Any laboratory that examines specimens, or reporting source finding evidence of HIV, shall permit the Division of Public Health to examine the records of said laboratory, facility, or office in order to evaluate compliance with Section 7.0 of this regulation.

7.4.2.3 Reports made based on perinatal HIV exposure shall be made regardless of confirmatory testing.

7.4.2.4 Reports of HIV/AIDS, required by subsection 7.4 shall be placed into the United States mail, using a special envelope that will be provided by the Division of Public Health, and routed to the Division within 48 hours of diagnosis, positive test, or treatment. Any other reporting method must be approved in advance and must be in a time frame acceptable to the Division.

7.4.2.5 As it is the intent of the Division of Public Health to continue the availability of anonymous HIV counseling and testing, and as it is not the practice to collect the name or other identifying information from a person who is anonymously tested for HIV, and therefore no name is available to be reported, nothing in this regulation shall preclude the performance of anonymous HIV testing.

7.4.3 Confidentiality of HIV/AIDS Reports

7.4.3.1 The Division of Public Health will evaluate reports of HIV/AIDS for completeness and potential referrals for service. All case reports will be kept in a confidential and in a secure setting.

7.4.3.2 The Division of Public Health will evaluate its procedures for HIV/AIDS named-based reporting on a continuous basis for timeliness, completeness of reporting, and security of confidential information.

7.4.3.3 The Division of Public Health will follow the December 10, 1999 Morbidity and Mortality Weekly Report Recommendations and Reports, "CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome" document as it pertains to patient records and confidentiality, or any subsequent revisions of said document.

7.4.3.4 All reports and notification made pursuant to Section 7.0 of this regulation are confidential and protected from release except under the provisions of 16 **Del.C.** §§710 and 711, §§1201 through 1204, and §§1201A through 1204A. Any person aggrieved by a violation of this section shall have a right of action in the Superior Court and may recover for each violation:

7.4.3.4.1 Against any person who negligently violates a provision of this regulation, damages of $1,000 or actual damages, whichever is greater.

7.4.3.4.2 Against any person who intentionally or recklessly violates a provision of subsection 7.4 of this regulation, damages of $5,000 or actual damages, whichever is greater.

7.4.3.4.3 Reasonable attorneys' fees.

7.4.3.4.4 Such other relief, including an injunction, as the court may deem appropriate.

7.4.3.4.5 Any action under this regulation is barred unless the action is commenced within 3 years after the cause of action accrues. A cause of action will accrue when the injured party becomes aware of an unauthorized disclosure.

7.4.3.5 From information received from reports of HIV infection, the Division of Public Health may contact attending physicians. The Division of Public Health shall inform the attending physician, if the notification indicates the person has an attending physician, before contacting a person on whom the report is made. However, if delays resulting from informing the physician may enhance the spread of HIV, or otherwise endanger the health of any individuals, the Division of Public Health may contact the person without first informing the attending physician.

7.4.4 Duty to Disclose the Identity of Sexual or Needle sharing Partners of HIV Infected Patients

7.4.4.1 Any health care provider diagnosing or caring for an HIV infected patient shall disclose the identity of the patient's sexual or needle-sharing partner or partners (if known), including spouses to the Division of Public Health so that the partner or partners may be notified of their risk of infection, provided that:

7.4.4.1.1 The provider knows of an identifiable partner at risk of infection who may not have been informed of their potential risk; and

7.4.4.1.2 The provider believes there is a significant risk of harm to the partner; and

7.4.4.1.3 Reasonable efforts have been made to counsel the patient pursuant to 16 **Del.C.** §1202(e), urging the patient to notify the partner, and the patient has refused or is unlikely to notify the partner.

7.4.4.2 Any health care provider diagnosing or caring for an HIV infected patient shall also report to the Division of Public Health relevant facts about a patient that does not pose a threat to an identifiable partner but, in the professional judgment of the provider based upon stated intended acts, the

patient may threaten further spread of HIV to the general population. In this instance the conditions specified in subsection 7.4.4.1.3 shall apply. Disclosure shall be for the purpose of providing appropriate counseling to the patient.

7.4.4.3 Procedures for disclosing information pursuant to this section shall be specified by the Division.

7.5 Tuberculosis

7.5.1 Any person afflicted with or suspected of being afflicted with tuberculosis disease and in need of hospitalization and unable to pay the cost, shall be hospitalized at public expense wherever and whenever facilities are available and provided that private or third-party funds are not available for this purpose.

7.5.2 Reporting Tuberculosis

7.5.2.1 Physicians, pharmacists, nurses, hospital administrators, medical examiners, morticians, laboratory administrators, and other health care providers who provide health care services to a person with diagnosed, suspected, or treated tuberculosis (TB) shall report such a case to the Division of Public Health.

7.5.2.1.1 Reports provided under this subsection shall specify the infected person's name, address, date of birth, race, ethnicity, gender, date of onset, site of disease, prescribed anti-TB medications, and, in the case of laboratory administrators, the name and address of the submitting health professional.

7.5.2.1.2 A report shall be telephoned into the Division of Public Health within 2 working days of the provision of service or laboratory finding.

7.5.2.2 Any person who oversees a clinical or hospital laboratory or other facility in which a laboratory examination of sputa, gastric contents, or any other specimen derived from human body yields microscopic, cultural, serological, or other evidence suggestive of tubercle bacilli shall notify the Division of Public Health by telephone within 2 working days of the occurrence.

7.5.2.3 Any health care provider who has knowledge about a person with multiple drug-resistant tuberculosis (MDR-TB), even if the confirmed or suspected TB cases had been previously reported, shall report the occurrence to the Division of Public Health within 2 days of the occurrence.

7.5.2.4 Persons with TB who have demonstrated an inability or an unwillingness to adhere to a prescribed treatment regimen, who refuse medication, or who show other evidence of not taking anti-TB medications as prescribed, shall be reported to the Division of Public Health within 2 days of the occurrence.

7.5.3 Diagnostic Examinations

7.5.3.1 Any persons suspected of having infectious tuberculosis shall have a tuberculosis skin or blood test, a chest radiograph, laboratory examination of sputum, gastric contents or other body discharges as may be required by the Division Director or designee to determine whether said patient represents an infectious case of tuberculosis.

7.5.3.2 The Division Director or designee shall determine the names of household and other contacts who may be infected with tuberculosis and cause them to be examined for the presence of tuberculosis disease.

7.5.4 Clinical Management

7.5.4.1 In addition to fulfilling the reporting requirements of subsection 7.5.2, health care providers shall manage persons with active TB disease by following 1 of 3 courses of action:

7.5.4.1.1 They shall immediately refer the client to the Division of Public Health for comprehensive medical and case management services; or

7.5.4.1.2 They shall provide comprehensive assessment, treatment, and follow-up services (including patient education, directly observed therapy and contact investigation) to the client and the client’s contacts consistent with current American Thoracic Society and the Centers for Disease Control and Prevention (ATS/CDC) guidelines; or

7.5.4.1.3 They shall initiate appropriate medical treatment and refer the client to the Division of Public Health for coordination of community services and case management including directly observed therapy (DOT).

7.5.4.1.3.1 If the health care provider chooses subsection 7.5.4.1.2 or 7.5.4.1.3 above, then the Division Director or designee may ask the health care provider for information about the care

and management of the patient, and the health care provider shall assure that the requested information is communicated.

7.5.4.2 Patients with infectious tuberculosis who are dangerous to public health may be required by the Division Director or designee to be hospitalized, isolated, or otherwise quarantined. Whenever facilities for adequate isolation and treatment of infectious cases are available in the home and patient will accept said isolation, it shall be left to the discretion of the Division Director or designee as to whether these or other facilities shall be used.

7.6 Healthcare-Associated Infections. By January 1, 2008, healthcare-associated infections shall be reported to the Centers for Disease Control and Prevention (CDC) through the National Healthcare Safety Network (NHSN) in accordance with the NHSN and the Department of Health and Social Service requirements and procedures as cited in 16 **Del.C.** Ch. 10A.

7.6.1 Definitions

For the purpose of Section 7.0 of this regulation, the following definitions shall apply:

"**Agency for Healthcare Research and Quality**" or "**AHRQ**" means an agency of the United States Department of Health and Human Services that works to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans and supports research that improves the quality of healthcare services.

"**Centers for Medicaid and Medicare Services**" or "**CMS**" means a branch of the United States Department of Health and Human Services that administers Medicare, Medicaid, and the Children's Health Insurance Program. CMS utilizes a system of payment for operating costs of healthcare facilities based on prospectively set rates. Rulings set forth by CMS have included specifications for use of NHSN for reporting certain healthcare-associated infections and other quality indicators for the purposes of monitoring and improving patient safety and quality of care.

"**Correctional facility**" means any medical unit operated within any Department of Correction facility in this State.

"**Department**" means the Delaware Department of Health and Social Services.

"**Dialysis center"** means a facility approved to furnish outpatient dialysis services directly to End Stage Renal Disease (ESRD) patients. Outpatient dialysis centers include staff-assisted dialysis (dialysis performed by the staff of the facility). ESRD is the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

"**Freestanding surgical center**" or "**FSSC**" means a facility that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization. The term does not include (1) a facility that is licensed as part of a hospital; (2) a facility that provides services or accommodations for patients who stay overnight; or (3) a facility that is used as an office or clinic for the private practice of a physician, podiatrist, or dentist.

"**Healthcare-associated infection**" or "**HAI**" means a localized or systemic condition that results from adverse reaction to the presence of an infectious agent or agents or its toxins; and that was not present or incubating at the time of admission to the healthcare facility.

"**Healthcare-Associated Infection Advisory Committee**" means a group that is appointed by the Secretary of the Department that includes 1 infection control professional who has responsibility for infection control programs from each hospital or health care system in Delaware, 4 infectious disease physicians with expertise in infection control, 1 representative from the Delaware Healthcare Facilities Association, 1 representative of a freestanding surgical center, 1 representative of a dialysis center, 1 representative of a psychiatric facility, and 1 representative from the State Division of Public Health, and the Public Health Healthcare-Associated Infections Specialist responsible for collating and reporting data. The Secretary shall also appoint 8 other members of the Committee including representatives from direct care nursing staff, academic researchers, consumer organizations, health insurers, health maintenance organizations, organized labor, and purchasers of health insurance, such as employers.

"**Healthcare-Associated Infection Specialist**" means a position established by the Department within the Division of Public Health supporting the functions of 16 **Del.C.** Ch. 10A. The Healthcare-Associated Infection Specialist must have knowledge of the National Healthcare Safety Network system and skills to appropriately analyze healthcare-associated infection data.

"**Healthcare facility**" means a correctional facility, dialysis center, freestanding surgical center, hospital, long-term care facility, psychiatric facility, or other facility as defined by the Centers for Medicaid and Medicare Services or the CDC.

"**Hospital**" means an acute care healthcare facility licensed under 16 **Del.C.** Ch. 10A.

"**Infection preventionist**" or "**IP**" means a registered nurse, physician, epidemiologist, or medical technologist who helps to prevent healthcare-associated infections by isolating source or sources of infections and limiting their spread. The IP systematically collects, analyzes, and interprets health data in order to plan, implement, evaluate, and disseminate appropriate public health practices. The IP also trains healthcare staff through instruction and dissemination of information on infection control practices.

"**Long-term acute care facility**" or "**LTAC**" means a long-term care hospital as defined by CMS. CMS defines long-term care hospitals as having an average length of stay of 25 days or more among all patients. Licensed LTACs are denoted by having the last 4 digits of the facility CMS Certification Number (CCN) between 2000 and 2299.

"Long-term care facility" means an institution such as a nursing home, skilled nursing facility, or intermediate care facility that provides healthcare to people who are unable to manage independently in the community.

"**National Healthcare Safety Network**" or "**NHSN**" means an internet-based surveillance system that is confidential. It is managed by the Division of Healthcare Quality Promotion at the CDC and used for the monitoring events associated with health care. The NHSN provides facilities and states with data needed to identify problem areas, measure progress of prevention efforts, and work toward eliminating healthcare-associated infections. It is the conduit for healthcare facilities to comply with CMS infection reporting requirements.

"**Psychiatric facility**" means a facility that is primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of persons with mental illness.

"**Public Report**" means the report provided to healthcare facilities and the public by the Department as set forth in 16 **Del.C**. §1003A(b).

"**Secretary**" means the Secretary of the Delaware Department of Health and Social Services.

7.6.2 Membership in NHSN

7.6.2.1 All hospitals in the State shall join the NHSN or its successor.

7.6.2.2 All outpatient dialysis centers in the State shall join the NHSN or its successor in accordance with CMS reporting specifications.

7.6.2.3 All LTACs in the State shall join the NHSN or its successor in accordance with CMS reporting specifications.

7.6.2.3.1 Every licensed LTAC (denoted by having the last 4 digits of the facility CMS Certification Number (CCN) between 2000 and 2299) shall join the NHSN as an individual LTAC facility with a unique NHSN facility ID number.

7.6.2.3.2 If an independently licensed LTAC location currently resides within an acute care or critical access facility type within NHSN, that LTAC location must be removed from the hospital and enrolled in NHSN as a separate facility and identified as a "HOSP-LTAC" facility type.

7.6.2.4 With concurrence of the HAI Advisory Committee, the Department may require other healthcare facilities through regulation to join the NHSN as may be appropriate in accordance with 16 **Del.C.** Ch 10A.

7.6.3 Persons and Institutions Required to Report

7.6.3.1 A physician who diagnoses and treats a healthcare-associated infection related to a clinical procedure, or a licensed practitioner who is permitted by law to diagnose and treat such infection and does so, is required to report the infection back to the healthcare facility at which the clinical procedure was performed. The infection control department of the healthcare facility will then be required to report to the Department only those infections that meet the accepted NHSN definitions and are currently required to be reported by law.

7.6.3.2 Hospitals shall report data on healthcare-associated infections and authorize the Department to have access to hospital-specific data contained in the NHSN database consistent with the requirements of 16 **Del.C.** Ch. 10A. Hospital staff assigned to fulfill the obligations of reporting

under this regulation shall be trained and shall follow the methods and procedures required by the NHSN as a condition of participation.

7.6.3.3 Correctional facilities shall report data on any healthcare-associated infections related to specific clinical procedures resulting from care in the correctional facility's medical unit consistent with the requirements of 16 **Del.C.** Ch. 10A.

7.6.3.4 Outpatient dialysis centers shall report data on healthcare-associated infections related to specific clinical procedures resulting from care in the facility as determined by CMS or the CDC and authorize the Department to have access to outpatient dialysis center-specific data contained in the NHSN database consistent with the requirements of 16 **Del.C.** Ch. 10A. Outpatient dialysis center staff assigned to fulfill the obligations of reporting under this regulation shall be trained and shall follow the methods and procedures required by the NHSN as a condition of participation.

7.6.3.5 LTACs shall collect data on healthcare-associated infections related to specific clinical procedures resulting from care in the facility as determined by CMS or the CDC and authorize the Department to have access to LTAC-specific data contained in the NHSN database consistent with the requirements of 16 **Del.C.** Ch. 10A. LTAC staff assigned to fulfill the obligations of reporting under this regulation shall be trained and shall follow the methods and procedures required by the NHSN as a condition of participation.

7.6.3.6 Other healthcare facilities required to join the NHSN, as determined by the HAI Advisory Committee, shall authorize the Department to have access to healthcare facility-specific data contained in the NHSN database consistent with the requirements of 16 **Del.C.** Ch. 10A. Staff of other healthcare facilities required to join the NHSN as determined by the HAI Advisory Committee that are assigned to fulfill the obligations of reporting under this regulation shall be trained and shall follow the methods and procedures required by the NHSN as a condition of participation.

7.6.4 Reporting of Data

7.6.4.1 Healthcare-associated infections required to be reported to the Department shall consist of the same HAIs required to be reported to CMS. In carrying out this requirement hospitals shall comply with the Hospital Inpatient Prospective Payment System final rule as published by CMS in the Federal Register.

7.6.4.2 Hospitals and other healthcare facilities as specified in this regulation shall report healthcare-associated infections pursuant to subsection 7.6.4.1 to the NHSN except for correctional facilities.

7.6.4.3 Correctional facilities shall report healthcare-associated infections consistent with subsection 11.3 on communicable diseases of this regulation.

7.6.4.4 In making such reports, healthcare facilities shall abide by the reporting procedures required for NHSN participation, including the frequency of reports, the information to be reported, and other standards required by the NHSN.

7.6.5 Hospital reports

7.6.5.1 Individual hospitals shall report to the Department those healthcare-associated infections required by CMS to be reported.

7.6.5.2 Infection preventionists, or a designee, of hospitals shall submit quarterly reports on their healthcare-associated infection data to the Department using the accepted NHSN definitions. Prevention and control data related to quality measures will be based on nationally recognized and recommended standards that may include those developed by the CDC, CMS, or the AHRQ.

7.6.6 Correctional facility reports

7.6.6.1 Correctional facilities shall report data on any healthcare-associated infections related to specific clinical procedures resulting from care in the correctional facility's medical unit. These categories of infection data may differ from that information required from hospitals.

7.6.6.2 A designee of the correctional facility shall submit quarterly reports on their healthcare-associated infection data to the Department using the accepted CDC, NHSN, or Department definitions. Prevention and control data related to quality measures will be based on nationally recognized and recommended standards that may include those developed by the CDC, CMS, or the AHRQ. The information from the correctional facilities shall be segregated from the hospital data contained in the reports submitted pursuant to 16 **Del.C.** Ch. 10A.

7.6.7 Outpatient dialysis center reports

7.6.7.1 Individual outpatient dialysis centers shall report to the Department those healthcare-associated infections required by CMS to be reported.

7.6.7.2 Infection preventionists, or a designee, of outpatient dialysis centers shall submit quarterly reports on their healthcare-associated infection data to the Department using the accepted NHSN definitions. Prevention and control data related to quality measures will be based on nationally recognized and recommended standards that may include those developed by the CDC, CMS, or the AHRQ.

7.6.8 Other healthcare facility reports

7.6.8.1 Only with the concurrence of the HAI Advisory Committee, and not until such time that CMS or CDC issue final federal regulations requiring such, and after careful evaluation of the economic and public health impact, the Department may through regulation require the reporting of healthcare-associated infections from healthcare facilities other than hospitals, correctional facilities, LTACs, and outpatient dialysis centers.

7.6.8.2 The procedures for reporting shall be consistent with procedures for reporting by hospitals as specified in this chapter, except as may be necessary to accommodate the unique characteristics and capabilities of the healthcare facilities and the capabilities of the NHSN.

7.6.9 Quarterly Reports

7.6.9.1 The Department will collate and prepare healthcare-associated infection data reported in NHSN by healthcare facilities quarterly and make these quarterly reports publicly available.

7.6.9.2 Data in quarterly reports must cover a period ending not earlier than 45 days prior to submission of the report.

7.6.9.3 Quarterly reports shall be made available to each healthcare facility 45 days after submittal to the Department for review by the healthcare facilities.

7.6.9.4 The healthcare facilities shall have 7 days to review the quarterly reports and report any changes to the Department. Following the 7-day review period, such quarterly reports shall be made available to the public at each hospital and through the Department (the "Public Report").

7.6.9.5 If the healthcare facility is a hospital that is a division or subsidiary of another entity that owns or operates other hospitals or related organizations, the quarterly report shall be for the specific division of or subsidiary and not for the other entity.

7.6.9.6 After June 30, 2010, and upon consultation with the HAI Advisory Committee and other experts in infection, prevention, identification and control, the Department may revise categories of infections set forth in subsection 7.6.4.1.

7.6.10 Annual Department reports

7.6.10.1 The Department shall annually submit to the legislature a report summarizing the hospital quarterly reports and shall publish the annual report on its website. Following the initial report, the Department shall update the public information on a quarterly basis.

7.6.10.2 All reports issued by the Department shall be risk adjusted or use some other method to account for the differences in patient populations among hospitals.

7.6.10.3 The annual report shall compare healthcare-associated infection rates to national rates (i.e. the use of standardized infection ratios [SIRs]) published by the NHSN program and collected pursuant to this chapter for each individual hospital in the State. The Department, in consultation with the HAI Advisory Committee, shall make this report as easy to comprehend as possible. The report shall also include an executive summary, written in plain language that shall include a discussion of findings, conclusions, and trends concerning the overall state of healthcare-associated infections in the State, including a comparison to prior years. The report may include policy recommendations, as appropriate.

7.6.10.4 The Department shall publicize the report and its availability as widely as practical to interested parties, including hospitals, providers, media organizations, health insurers, health maintenance organizations, purchasers of health insurance, organized labor, consumer or patient advocacy groups and individual consumers. The annual report shall be made available to any person upon request.

7.6.10.5 No healthcare facility report or Department disclosure may contain information identifying a patient, employee, or licensed health care professional in connection with a specific infection incident, pursuant to 16 **Del.C.** Ch. 10A.

7.6.10.6 The annual report shall provide background information about each hospital, which shall include: the hospital's adult and pediatric populations, bed size, and specialty divisions, whether the hospital provides tertiary care, and whether the hospital is a teaching or nonteaching institution. This background information shall be included in the Public Report.

7.6.10.7 The annual report shall include a brief summary to allow hospitals to comment on performance improvement and changes in patient population and risk factors. The information contained in the summary report shall be considered proprietary information and shall be utilized by the Department but shall not be made available in the Public Report and shall not be subject to disclosure under the State's Freedom of Information Act [29 **Del.C.** Ch. 100].

7.6.11 Healthcare-Associated Infection Advisory Committee

7.6.11.1 The HAI Advisory Committee engages personnel with appropriate training or certification in infection prevention and control for the purposes of collecting data.

7.6.11.2 The HAI Advisory Committee shall assist the Department in the development of all aspects of the Department's methodology for collection, analyzing, and disclosing the information collected under 16 **Del.C.** Ch. 10A including collection methods, formatting, and methods and means for release and dissemination.

7.6.11.3 In developing the methodology for collecting and analyzing the infection rate data, the Department and the HAI Advisory Committee shall adopt the methodologies and system for data collection from the NHSN or its successor. The data collection and analysis methodology shall be disclosed to the public prior to any public disclosure of healthcare-associated infection rates.

7.6.11.4 The HAI Advisory Committee shall assist the Department in the sharing of information and best practices toward the development of activities and policies that:

7.6.11.4.1 Enhance coordination between healthcare facilities throughout the continuum of care for the prevention and control of healthcare-associated infections;

7.6.11.4.2 Promote the prevention and control of healthcare-associated infections generally; and

7.6.11.4.3 Encourage the creation of benchmarks against which to measure progress in the prevention and control of healthcare-associated infections.

7.6.12 Privacy. It is the express intent of the legislature that a patient's right of confidentiality shall not be violated in any manner. Patient Social Security numbers and any other information that could be used to identify an individual patient shall not be released notwithstanding any other provision of law.

7.6.13 Penalties

7.6.13.1 A determination that a healthcare facility has violated the provisions of this chapter may result in any of the following:

7.6.13.1.1 Termination of licensure or other sanctions relating to licensure under Chapter 10 of this title; or

7.6.13.1.2 A civil penalty of up to $500 per day per violation for each day the healthcare facility is in violation of 16 **Del.C.** Ch. 10A.

7.6.14 Regulatory oversight. The Department shall be responsible for ensuring compliance. When the Department licenses a healthcare facility according to the provisions of this title, compliance with this chapter shall be a condition of licensure.

7.6.15 Privilege and confidentiality protections. Notwithstanding any other provision of federal, state, or local law, the healthcare-associated infection data provided pursuant to this chapter is privileged and, except for §§1003A, 1004A and 1005A of 16 **Del.C.** Ch. 10A., shall not be:

7.6.15.1 Subject to admission as evidence or other disclosure in any federal, state, or local civil, criminal, or administrative proceeding; or

7.6.15.2 Subject to use in a disciplinary proceeding against a healthcare facility or provider; or

7.6.15.3 Subject to disclosure under 29 **Del.C.** Ch. 100.

9 DE Reg. 1188 (02/01/06)
12 DE Reg. 1418 (05/01/09)
15 DE Reg. 1163 (02/01/12)
17 DE Reg. 320 (09/01/13)
22 DE Reg. 1012 (06/01/19)
23 DE Reg. 665 (02/01/20)

24 DE Reg. 791 (02/01/21)
27 DE Reg. 863 (05/01/24)

8.0 Preparation for Burial

See 16 **Del.C.** Ch. 31 and Department of Health and Social Services regulations promulgated thereunder, 16 **DE Admin. Code** 4204 Care and Transportation of the Dead.

9 DE Reg. 1188 (02/01/06)
22 DE Reg. 1012 (06/01/19)
27 DE Reg. 863 (05/01/24)

9.0 Disposal of Infectious Articles, Remains

No person shall dispose of articles, or human or animal remains known or suspected to be capable of infecting others with a communicable disease in such a manner whereby exposure to such infectious agents may occur. See also 16 **DE Admin. Code** 4204 Care and Transportation of the Dead, Section 10.0 ("Disposition of Amputated Parts of Human Bodies").

9 DE Reg. 1188 (02/01/06)
22 DE Reg. 1012 (06/01/19)
27 DE Reg. 863 (05/01/24)

10.0 Diseased Animals

10.1 Importation and Sale. No person shall bring into this state or offer for sale domestic or wild animals infected or suspected to be infected with a disease communicable from animals to man.

10.2 Notification. It shall be the duty of persons having custody of care of animals infected or suspected to be infected with a disease transmitted from animals to man to notify the Division Director or designee of the infection.

9 DE Reg. 1188 (02/01/06)
22 DE Reg. 1012 (06/01/19)
23 DE Reg. 665 (02/01/20)

11.0 Notification of Emergency Medical Care Providers of Exposure to Communicable Diseases

11.1 For the purposes of Section 11.0 of this regulation, the following definitions shall apply.

"**Emergency medical care provider**" means a fire fighter, law enforcement officer, paramedic, emergency medical technician, correctional officer, ambulance attendant, or other person who serves as employee or volunteer of an ambulance service or provides prehospital emergency medical service.

"**Receiving medical facility**" means a hospital or similar facility that receives a patient attended by an emergency medical care provider for the purposes of continued medical care.

"**Standard precautions**" means those precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments, that minimize the risk of transmission of communicable diseases between patients and health care providers. Standard precautions require that all care providers use appropriate barrier precautions to prevent exposure to blood and body fluids, secretions, and excretions of all patients at all times.

11.2 Standard Precautions

11.2.1 Didactic Instruction. Education and training with respect to standard precautions shall be a mandatory component of any required training and any required continuing education for all emergency medical care providers who have patient contact. Training shall be appropriately tailored to the needs and educational background of the emergency medical care providers being trained. Training shall include the following:

11.2.1.1 Mechanisms and routes of transmission of viral, bacterial, rickettsial, fungal, and mycoplasmal human pathogens.

11.2.1.2 Proper techniques of hand washing, including the theory supporting the effectiveness of hand washing, and guidelines for waterless hand cleansing in the field.

11.2.1.3 Proper techniques and circumstances under which barrier methods of protection (personal protective equipment) from contamination by microbial pathogens are to be implemented. The instruction is to include the theory supporting the benefits of these techniques.

11.2.1.4 Proper techniques of disinfection and cleanup of spills of infectious material. This instruction is to include the use of absorbent, liquid, and chemical disinfectants.

11.2.1.5 Instruction regarding the reporting and documentation of exposures to infectious agents and the requirement for employers to have an exposure control plan.

11.2.1.6 Proper disposal of contaminated needles and other sharps. The instruction is to include information about recapping needles and using puncture-resistant, leak-resistant containers, and safety sharps.

11.2.1.7 First aid and immediate care of wounds that may be incurred by an emergency medical care provider.

11.2.2 Practical or Laboratory Instruction

11.2.2.1 Practical sessions addressing the field application of the above didactic instruction must be part of the curriculum.

11.2.2.2 The practical sessions shall provide a means of hands-on experience and training in the following:

11.2.2.2.1 The proper use of personal protective equipment, hand-washing disinfection, cleanup of infectious spills, handling and disposal of contaminated sharps, and the proper completion of reporting forms.

11.2.3 Approval of Curricula. Any provider of mandatory education and training and continuing education pursuant to this section must submit a curriculum for approval by the Division of Public Health and shall not utilize curricula that are not regarded by the Division of Public Health to be in substantial compliance with subsections 11.2.1 and 11.2.2.

11.3 Communicable Diseases

11.3.1 Communicable Disease Defined. For the purposes of Section 11.0 only, exposure to patients infected with the following communicable disease agents shall warrant notification to an emergency medical care provider pursuant to this section:

11.3.1.1 Human Immunodeficiency Virus (HIV)

11.3.1.2 Hepatitis B Virus

11.3.1.3 Hepatitis C Virus

11.3.1.4 Meningococcal disease

11.3.1.5 *Haemophilus influenzae*

11.3.1.6 Measles

11.3.1.7 Tuberculosis

11.3.1.8 Uncommon or rare pathogens

11.3.2 Infection Defined. For the purposes of Section 11.0 only, a patient shall be considered infected with a communicable disease when the following conditions are satisfied:

11.3.2.1 Blood-borne pathogens

11.3.2.1.1 HIV: ELISA and western blot (or other confirmatory test accepted by prevailing medical opinion) tests must be positive.

11.3.2.1.2 Hepatitis B: Positive for Hepatitis B surface antigen.

11.3.2.1.3 Hepatitis C: Hepatitis C antibody screening test and more specific supplemental test positive.

11.3.2.2 Airborne and droplet-spread pathogens

11.3.2.2.1 Meningococcal disease: Compatible clinical findings and laboratory confirmation through isolation of *Neisseria meningitidis* from a normally sterile site.

11.3.2.2.2 *Haemophilus influenzae*: Compatible clinical findings of epiglottitis or meningitis and laboratory confirmation through isolation of *Haemophilus influenzae* from a normally sterile site or from the epiglottis.

11.3.2.2.3 Measles: Compatible clinical findings with or without laboratory confirmation by 1 of the following methods:

11.3.2.2.3.1 Presence of the measles virus from a clinical specimen;

11.3.2.2.3.2 Four-fold rise in measles antibody level by any standard serologic assay; or

11.3.2.2.3.3 Positive serologic test for measles IgM antibody.

11.3.2.2.4 Tuberculosis: Compatible clinical findings of pulmonary disease and identification of either acid-fast bacilli in sputum or the pathogen by culture.

11.3.2.3 Uncommon or rare pathogens. Infection with uncommon or rare pathogens determined by the Division of Public Health on a case-by-case basis.

11.3.3 Exposure Defined

11.3.3.1 Blood-borne pathogens. Exposure of an emergency medical care provider to a patient infected with a blood-borne pathogen as defined in subsection 11.3.2.1 shall include a needle-stick or other penetrating injury with an item contaminated by a patient's blood, plasma, pleural fluid, peritoneal fluid, tissue, cerebrospinal fluid, synovial fluid, peritoneal fluid, pericardial fluid, amniotic fluid, or any other body fluid or drainage that contains blood or plasma. Contact of these fluids with mucous membranes or non-intact skin of the emergency medical care provider or extensive contact with intact skin shall also constitute exposure.

11.3.3.2 Airborne and droplet-spread pathogens. Exposure of an emergency medical care provider to a patient infected with an airborne or droplet-spread pathogen as defined in subsection 11.3.2.2 shall be as follows:

11.3.3.2.1 Meningococcal disease and *Haemophilus influenza*: Close contact with an infected patient's oral secretions or sharing the same air space with an infected patient for 1 hour or longer without the use of an effective barrier such as a mask.

11.3.3.2.2 Measles: Sharing confined air space with an infected patient, regardless of contact time.

11.3.3.2.3 Tuberculosis: Sharing confined air space with an infected patient, regardless of contact time.

11.3.3.3 Uncommon or rare pathogens. The Division of Public Health shall determine definition of exposure to an uncommon or rare pathogen on a case-by-case basis.

11.3.3.4 Ruling on infection and exposure. When requested by the emergency medical care provider or receiving medical facility, the Division of Public Health shall investigate and issue judgment on any differences of opinion regarding infection and exposure as otherwise defined in subsection 11.3.

11.4 Request for Notification

11.4.1 Every employer of an emergency medical care provider and every organization which supervises volunteer emergency medical care providers must register the name or names of a designated officer who shall perform the following duties. The designated officer shall delegate these duties as may be necessary to ensure compliance with this regulation.

11.4.1.1 Receive requests for notification from emergency medical care providers;

11.4.1.2 Collect facts relating to the circumstances under which the emergency medical care provider may have been exposed;

11.4.1.3 Forward requests for notification to receiving medical facilities;

11.4.1.4 Report to the emergency medical care provider findings provided by the receiving medical facility; and

11.4.1.5 Assist the emergency medical care provider to take medically appropriate action if necessary.

11.4.2 Receiving medical facilities must register with the Division of Public Health the name or office to whom notification requests should be sent by an emergency medical care provider and who is responsible for ensuring compliance with this section.

11.4.3 If an emergency medical care provider desires to be notified under this regulation, the officer designated pursuant to subsection 11.4.1 shall notify the receiving medical facility within 24 hours after the patient is admitted to or treated by the facility on a form that is prescribed or approved by the State Board of Health.

11.5 Notification of Exposure to Airborne and Droplet-Spread Pathogens

11.5.1 Notwithstanding any requirement of subsection 11.4.3, a receiving medical facility must make notification when an emergency medical care provider has been exposed to an airborne or droplet-spread communicable disease pursuant to subsections 11.3.2.2 and 11.3.3.2. Such notification shall occur as soon as possible but not more than 48 hours after the exposure has been determined and shall apply to any patient upon whom such a determination has been made within 30 days after the patient is admitted to or treated by the receiving medical facility.

11.5.2 To determine if notification is necessary pursuant to this section, a receiving medical facility must review medical records of a patient infected with an airborne or droplet-spread communicable disease to

determine if care was provided by an emergency medical care provider. If medical records do not so indicate, the receiving medical facility shall assume that no notification is required.

11.6 Notification of Exposure when Requested

11.6.1 When a request for notification has been made pursuant to subsection 11.4.3, the receiving medical facility shall attempt to determine if the patient is infected with a communicable disease and if the emergency medical care provider has or has not been exposed. Information provided on the request for notification and medical records and findings in possession of the receiving medical facility shall be used to make this determination. If a determination is made within 30 days after the patient is admitted to or treated by the receiving medical facility, the receiving medical facility shall notify the officer designated pursuant to subsection 11.4.1 as soon as possible but not more than 48 hours after the determination. The following information shall be provided in the notification:

11.6.1.1 The date that the patient was attended by the emergency medical care provider;

11.6.1.2 Whether or not the emergency medical care provider was exposed; and

11.6.1.3 If the emergency medical care provider was exposed, the communicable disease involved.

11.6.2 If, after expiration of the 30-day period and because of insufficient information, the receiving medical facility has not determined that the emergency medical care provider has or has not been exposed to a communicable disease, the receiving medical care facility shall so notify the officer designated pursuant to subsection 11.4.1 as soon as possible but not more than 48 hours after expiration of the 30-day period. The following information shall be provided in the notification:

11.6.2.1 The date that the patient was attended by the emergency medical care provider; and

11.6.2.2 That there is insufficient information to determine if an exposure has occurred.

11.6.3 The receiving medical facility shall provide to the Division of Public Health a copy of each form completed pursuant to subsection 11.4 which shall include information about whether or not the patient is infected, and if the emergency medical care provider is considered by the receiving medical facility to have been exposed.

11.7 Manner of Notification

11.7.1 A receiving medical facility must make a good faith effort, which is reasonably calculated based upon the health risks, the need to maintain confidentiality, and the urgency of intervention associated with the exposure, to expeditiously notify the officer designated pursuant to subsection 11.4.1.

11.7.2 If notification is by mail, and if, in the judgment of the receiving medical facility the circumstances warrant, the receiving medical facility shall ensure by telephone or other appropriate means that the designated officer of the emergency medical care provider has received notification.

11.8 Transfer of Patients

11.8.1 If, within the 30-day limitation defined in subsections 11.5.1 and 11.6.1 a patient is transferred from a receiving medical facility to a second receiving medical facility, the receiving medical facility must provide the second facility with all requests for notification made by emergency medical care providers for that patient.

11.8.2 The second receiving medical facility must make notification to the officer designated pursuant to subsection 11.4.1 if the facility determines within the remaining part of the 30-day period that the patient is infected and shall otherwise comply with this regulation.

11.9 Death of Patient

11.9.1 If, within the 30-day limitation defined in subsections 11.5.1 and 11.6.1, a patient is transferred from a receiving medical facility to a medical examiner, the receiving medical facility must provide the medical examiner with all requests for notification made by emergency medical care providers for that patient.

11.9.2 The medical examiner must make notification to the designated officer if the medical examiner determines that the patient is infected with a communicable disease and shall otherwise comply with this regulation.

11.10 Testing of Patients for Infection. Nothing in this regulation shall be construed to authorize or require a medical test of an emergency medical care provider or patient for any infectious disease.

11.11 Confidentiality. All requests and notifications made pursuant to this regulation shall be used solely for the purposes of complying with this regulation and are otherwise confidential.

9 DE Reg. 1188 (02/01/06)

17 DE Reg. 320 (09/01/13)

22 DE Reg. 1012 (06/01/19)

23 DE Reg. 665 (02/01/20)
24 DE Reg. 791 (02/01/21)
27 DE Reg. 863 (05/01/24)

APPENDIX I
State of Delaware - List of Reportable Diseases/Conditions

AIDS / HIV Stage III (S)
Acute flaccid myelitis
Alpha gal syndrome
Amebiasis
Anaplasmosis
Anthrax (T)
Arboviral human infections:
- Anaplasmosis
- Cache Valley virus disease
- California encephalitis virus disease
- California serogroup virus diseases
- Chikungunya virus disease
- Colorado tick fever virus disease
- Eastern equine encephalitis virus disease
- Jamestown Canyon virus disease
- Japanese encephalitis virus disease
- Keystone virus disease
- La Crosse virus disease
- Powassan virus disease
- Snowshoe hare virus disease
- St. Louis encephalitis virus disease
- Tick-borne encephalitis viruses
- Trivittatus virus disease
- West Nile virus disease
- Western equine encephalitis virus disease
- Venezuelan equine encephalitis virus
- Zika virus disease
- Other Arboviral diseases, not otherwise specified

Babesiosis
Botulism (T)
Brucellosis (T)
Campylobacteriosis
Candida auris
Carbapenemase-Producing Organisms (CPO)
Carbon monoxide poisoning
Chancroid (S)
Chickenpox (Varicella)
Chlamydia (S)
Cholera (toxigenic *Vibrio cholerae* 01 or 0139) (T)
Coccidioidomycosis
Coronavirus, novel (novel coronavirus causing severe acute respiratory disease including the 2019 novel coronavirus disease [COVID-19], severe acute respiratory syndrome-associated coronavirus disease [SARS-CoV], and Middle East Respiratory Syndrome [MERS-CoV]) (T)

Creutzfeldt-Jakob Disease (T)
Cronobacter infection
Cryptosporidiosis
Cyclosporiasis
Cytomegalovirus (neonatal only)
Dengue virus infections (T)
Diphtheria (T)
Ehrlichiosis
Encephalitis
Enterobacteriaceae, carbapenem-resistant (invasive or urine only) (A)
Escherichia coli, Shigatoxin producing (STEC) (T)
ESBL B-lactamases-invasive only (A)
Foodborne Disease Outbreak (T)
Free living amebae infections
Giardiasis
Glanders (T)
Gonorrhea (S)
Granuloma inguinale (S)
Guillain-Barre
Haemophilus influenzae, invasive
Hansen's Disease (Leprosy)
Hantavirus (T)
Hemolytic Uremic Syndrome (T)
Hepatitis A (T)
Hepatitis B
Hepatitis C
Hepatitis Other
Herpes, congenital (S)
Herpes, genital (S)
Histoplasmosis
HIV (S)
Human Papillomavirus (S)
Influenza
Influenza-associated pediatric mortality (T)
Kawasaki Syndrome
Lead, child blood, all test results
Legionellosis
Leptospirosis
Listeriosis
Lyme Disease
Lymphogranuloma venereum (S)
Malaria
Measles (T)
Melioidosis
Meningitis, Aseptic
Meningitis, Bacterial other
Meningococcal disease (*Neisseria meningitidis*) (T)
Mpox virus infection (T)
Mumps (T)

Norovirus
Nosocomial (Healthcare-Associated) Disease Outbreak (T)
Pelvic Inflammatory Disease (*N. gonorrhoeae, C. trachomatis*, or unspecified) (S)
Pertussis (T)
Plague (T)
Poliomyelitis (T)
Psittacosis
Q Fever
Rabies (human and animal) (T)
Respiratory Syncytial virus-associated deaths (RSV)
Reye Syndrome
Rheumatic Fever
Ricin Toxin (T)
Rickettsial Disease
Rubella (including congenital, which is rapidly reportable [T])
Salmonellosis
Shigellosis
Silicosis
Smallpox (T)
Spotted fever rickettsiosis
Staphylococcal aureus, Vancomycin Intermediate or Resistant (VISA, VRSA) (T)
Staphylococcal Enterotoxin (T)
Streptococcal Disease, invasive
Streptococcus pneumoniae, invasive (A)
Syphilis, all stages (S)
Tetanus (T)
Toxic Shock Syndrome (Streptococcal or Staphylococcal)
Toxoplasmosis
Trichinellosis
Tuberculosis (T)
Tularemia (T)
Typhoid Fever (T)
Typhus Fever (endemic flea borne, louse borne, tick borne)
Vaccine Adverse Reaction
Vancomycin resistant Enterococcus, invasive only
Vibrio, non-cholera
Viral Hemorrhagic Fevers (T)
Waterborne Disease Outbreaks (T)
Yellow Fever (T)
Yersiniosis

2. Reporting timeframe

(T) - call or email within 4 hours
(S) - sexually transmitted disease, report required within 24 hours
(A) - Drug-Resistant Organisms required to be reported within 48 hours
All others - report required within 48 hours

9 DE Reg. 1188 (02/01/06)
12 DE Reg. 1418 (05/01/09)
17 DE Reg. 320 (09/01/13)

23 DE Reg. 665 (02/01/20)
24 DE Reg. 791 (02/01/21)
27 DE Reg. 863 (05/01/24)

APPENDIX II
Organisms and Samples to be sent to the Delaware Public Health Laboratory

1. All laboratories located in Delaware and laboratories that have specimen collection sites in Delaware, including those laboratories with testing or processing facilities located out of state, are required to submit suspected and confirmed isolates and clinical materials of proposed agents from Delaware residents to the DPHL.

2. All clinical or hospital laboratories, or other facilities, located in Delaware that presumptively identify or are unable to rule out biothreat organisms shall notify immediately and send an isolate, clinical material, or specimen to the DPHL for testing as soon as possible. Those located outside the State, should contact their nearest State Laboratory or Laboratory Response Network laboratory.

3. All other isolates and clinical specimens of microorganism listed in item 4. below shall be sent to the DPHL.

4. List of microorganisms to send to the DPHL:

4.1 Select Agent organisms (notify DPHL immediately, by secure email or telephone, prior to sending for confirmation within 24 hours of suspicion of clinical presentation for the following agents:

Bacillus anthracis/Bacillus cereus biovar anthracis
Brucella species
Burkholderia mallei
Burkholderia pseudomallei
Clostridium botulinum
Coxiella burnetii
Francisella tularensis
Ebola and other viral hemorrhagic viruses
Middle Eastern Respiratory Syndrome coronavirus (MERS-CoV)
Mpox virus
SARS-Coronavirus (CoV)/SARS-CoV-2 Chimeric viruses
Vaccinia virus
Variola (smallpox) virus
Yersinia pestis

4.2 Emerging Infectious Organisms of Public Health Concern - (notify DPHL immediately, by secure email or telephone, prior to sending for confirmation within 24 hours of suspicion of clinical presentation for the following agents:

Measles and Mumps virus
Mycobacterium tuberculosis complex
Haemophilus influenzae and Neisseria meningitidis from sterile body sites
Any agent suspected of displaying cluster/outbreak potential

Any individual cases displaying unusual patterns of antimicrobial resistance (including non-susceptibility to all tested antimicrobials), atypical virulence/resistance genetic mechanisms, or emerging infectious pathogen or pathogens.

4.3 Surveillance (Foodborne/Respiratory) (send within 3 - 5 business days, prior notification to lab not required)

Campylobacter species (minimum 2 samples per month per submitter)
Cronobacter species
COVID-19 (minimum 2 samples per week per submitter)
Influenza (minimum 2 samples per day per submitter during outbreak season)
Listeria monocytogenes
Norovirus (2 samples per month per submitter)
Salmonella species
Shiga toxin producing Escherichia coli (STEC)
Shigella species
Vibrio species
Yersinia enterocolitica

4.4 Antimicrobial resistance (send within 3 - 5 business days, prior notification of lab not required).

Candida auris
Neisseria gonorrhoeae, (cases suspected of antimicrobial resistance/treatment failure)
Staphylococcus aureus, Vancomycin resistant (VRSA)
Carbapenem resistant organisms (CRO) including Enterobacteriaceae (CRE) Acineto-bacter baumannii (CRAB), and Pseudomonas aeruginosa (CRPA)

5. Any environmental sample deemed as credible threats for harboring a toxin or a biological agent of terrorism shall be sent to the DPHL for testing immediately upon identification. Organizations must notify DPHL, by secure email/phone, prior to submitting for testing.

6. Clinical specimens from patients potentially exposed to a chemical agent of terrorism shall be sent to the DPHL for testing immediately upon identification.

9 DE Reg. 1188 (02/01/06)
12 DE Reg. 1418 (05/01/09)
15 DE Reg. 1163 (02/01/12)
17 DE Reg. 320 (09/01/13)
22 DE Reg. 1012 (06/01/19)
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