DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 1008A (16 **Del.C.** §1008A)
16 **DE Admin. Code** 4202

FINAL

4202 Control of Communicable and Other Disease Conditions

Nature of the Proceedings

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Hospital Acquired Infections. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Del.C.** Ch. 101 and authority as prescribed by 16 **Del.C.** §1008A.

On January 1, 2009 (Volume 12, Issue 7), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by January 30, 2009, or be presented at a public hearing on January 29, 2009, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written and verbal comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

Findings of Fact

Based on comments received, non-substantive changes were made to the proposed regulations. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Home Health Agencies are adopted and shall become effective April 10, 2009, after publication of the final regulation in the Delaware Register of Regulations.

Rita M. Landgraf

April 1, 2009, RITA M. LANDGRAF
SECRETARY

Summary of Evidence

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Hospital Acquired Infections were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*. Verbal and written comments were received on the proposed regulations during the public comment period (January 1, 2009 through January 30, 2009). Entities offering written comments included:

State Council for Persons with Disabilities
Governor's Advisory Council for Exceptional Citizens
Nemours/A.I. duPont Hospital for Children

Medical Society of Delaware

Public comments and the DHSS (Agency) responses are as follows:

The regulation sometimes refers to the codified version of the enabling legislation. See, e.g., §7.6 reference to 16 **Del.C.** Ch. 10A. Other sections refer to the statutes at large reference. See, e.g., §7.6.1 definition of "Public Report"; §7.6.2.2; and §7.6.6. It would be preferable to consistently use citations to the codified law which facilitates web-based access.

Agency Response: The Agency agrees and for purposes of consistency will make the change from "**76 Del. C. Ch. 10A"** in **§7.6.1, §7.6.2.2 and §7.6.6 to** "**16 Del. C. Ch. 10A**.".

In §7.6.1, definition of "Centers for Disease Control and Prevention", it would be preferable to substitute "which" for "who". The antecedent of the relative pronoun is "agency".

Agency Response: The Agency agrees and will substitute "which" for "who."

In §7.6, definition of "National Healthcare Safety Network", consider deletion of "voluntary". It is not a necessary part of the definition and there is some tension between the representation that the system is voluntary when §7.6.2.1 and Title 16 **Del.C.** §1011A make enrollment mandatory.

Agency Response: The Agency agrees and to avoid any confusion will delete "voluntary" in the definition of National Healthcare Safety Network.

Unless contained in another DPH regulation, the Division may wish to consider incorporation of a penalty provision for non-compliance to conform to Title 16 **Del.C.** §1007A. The Division could also consider incorporation of standards covering the annual report required by Title 16 **Del.C.** §1004A. Under the latter statute, the initial report must be published no later than June 30, 2009.

Agency Response: The penalties for violation of the Act have been set by the General Assembly in §1007A of the Hospital Infections Disclosure Act.

We applaud the State's attempt to improve the health of Delawareans by monitoring hospital-acquired infections. We are concerned with just one provision of the proposed regulation, however, namely section 7.6.3.1, which is copied below with a revision. This provision defines the reporting requirement for physicians. We recognize the need for and importance of this reporting, but the scope of this provision is overly broad and would impose an onerous burden on physician practices, which are already burdened by administrative hassles from the insurance companies. Setting aside the most obvious cases, how are physicians to know which infections were acquired in the hospital? This opens the door for requiring all infections to be reported, which besides creating a new burden on physician practices, would also skew the data on these infections. We suggest amending the provision simply by inserting the word "obviously" after the word "any" and before "hospital-acquired".

Suggested to read: 7.6.3.1 Physicians, who perform a clinical procedure, shall report to the ICP of the hospital where the clinical procedure was performed any <u>obviously</u> hospital-acquired infection that the physician diagnosed at a follow-up appointment with the patient.

Agency Response: The Agency respectfully disagrees.

There is no "cost impact" in the regulations – this is important and is usually included, it should be. I know for the State of DE if the FTE cost (to the state) is over $50,000 a regulation must pass to fund that aspect.

Agency Response: Section 3 of the Act as enacted into law provided that the Hospital Infections Disclosure Act would only 'become effective upon the specific appropriation of funds for such purposes in the Annual Appropriations Act.' The Agency believes it has complied in all respects with the law.

Section 2.2.1 within 48 hours of recognition or "diagnosis"?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 2.3 “Ordinary Skill” – this seems vague. I suggest adding within their credentialed/scope of expertise. Also, “diagnosis” is more crucial than “impression” – this regulation promotes a lot of false alarms.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 3.0 – who decides what is of public concern? How do define “outbreak” – 1? This implies knowing normal rate variation which would not be concerning if “experts” were determining this rather than local “labs” or “persons of ordinary skill”.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 3.2.2 has lots of words like “unusual”, “may” – again, what is the impact of a false alarm – why not just require a “diagnosis” on the prescription?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 4.2 is confusing as to who is actually making the reports?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Attending physicians should be notified of all investigations as they will have best knowledge of the indications – the regulations are not uniform in requiring this.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 4.4 is very hard to read or understand – can it be explained?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 5.3.3.2 and 5.3.3.3 both mention general symptoms as potential cause for alarm – all these symptoms can exist and do in common viral infections. I believe it is key to work off diagnosis rather than symptoms – we have diagnostic tools that diagnose within hours.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 6.2.1 – quarantine should include making a diagnosis by a certified/board eligible expert.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 6.7.3 through 6.8.1 – a major concern because if you process flow the timeline, a person could be "held" in isolation against their will for over 30 days (!!!!) before a definitive diagnosis or proper due process is performed or required. This has to be reviewed and changed – this represents a very important Civil Liberties issue.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 7.1.1 and all vaccination/immunization sections – issues the words "must be" are present. I assume this is not a change from current practice?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 7.3.2.5 contains the notification of Attending provision but only after the Division of Public Health determines to do it – my concern is that the "medical facts of the case" can take many directions without this contact being required early in the process.

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 7.6.1 – how do they "risk adjust"? This is key as it identifies trends BUT the regulations also assume that a local lab tech or lab director or Attending can do the same without this knowledge – how can that be?

Agency Response: National Healthcare Safety Network (NHSN) automatically "risk adjusts" the data that are entered into this system. Therefore, a local lab tech, lab director, or Attending can put the raw data into the system and the system will "risk adjust" the raw data based on the data collected. This is one of the reasons for all the hospitals to participate in the NHSN.

In section 7.6.4.1 reporting of data – why not just use those infections in the "Never Events" of CMS? It would avoid administrative duplication, make sense and provide a potential avenue to track cost savings rather than burden with extra costs of reporting.

Agency Response: The Agency appreciates your comments; however, the Hospital Infection Act states that Hospital Acquired Infection Advisory Committee will determine the clinical procedure and the data that will be reported to the Department.

Data will be tracked monthly but reported quarterly I believe the regs are trying to say.

Agency Response: National Health Safety Network accepts data monthly; therefore, the Agency agrees that data will be entered monthly and the reports will be available quarterly. The Agency will make this change in section 7.6.3.2. The section will read as follows: "The hospital's reporting officer or his or her designee shall submit **monthly** data on his or her hospital acquired infection rates to the Department through the NHSN, using the accepted CDC's NHSN definitions."

Section 7.6.5.1.2 Physicians names are included? Why? Will it include outpatient? Are you targeting only ICU patients hence adding selection bias?

Agency Response: The Agency will not include names of the physicians, outpatients, employees, and/or any identifying information in connection with a specific infection incident. This is stated in Section 7.6.6. The Hospital Acquired Infection Advisory Committee determines the clinical procedures, and examples of these are stated in Section 1003A in the Hospital Infection Disclosure Act. The data collected for this Act do not only include ICU patients. The data may also include other samples of population depending on what the Advisory Committee decides in the future.

Finally, a process flow map should be performed as I believe the Regulations do not provide an easy means to explain the reporting – each step in the process should include roles and responsibilities and a "chain of command to verify reports". In looking at the report, I believe there are a few inconsistencies.

Agency Response: The Agency appreciates your comments but at this time, a process flow map will not be included.

Under the list of Diseases/Conditions is listed "nosocomial" but there is no definition or clarification except for Central line infections – this has to be explained more or perhaps the regulations can spell out or reference the source of when an "outbreak" is determined. We have had, for example, many "scares" of nosocomial outbreaks – we have experienced the lack of clarity as to some of these issues - can there be included more guidance? Can we define "vaccine adverse reaction"? "Haemophilus influenzae, sterile sites" – all types?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

Section 11.6 Do we report who gets prophylaxis?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

The Regulations do not spell out the impact on the hospitals – i.e. when to close a unit, the impact of "colonization" on the workforce (when is colonization a concern and should limit work?), is there a workman's compensation potential issue if identified?

Agency Response: The Agency appreciates your comments but we are only taking comments from the public on the Hospital Acquired Infections section of the Regulations for the Control of Communicable and Other Disease Conditions. When we do have a full review of these regulations, we are happy to address your comments at that time.

In addition to non-substantive amendments mentioned above, minor grammatical or technical corrections were made to further clarify the proposed regulations.

The public comment period was open from January 1 – January 30, 2009.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

4202 Control of Communicable and Other Disease Conditions

1.0 Definitions

The following terms shall mean:

"Carrier" A person who harbors pathogenic organisms of communicable disease but who does not show clinical evidence of the disease and serves as a potential source of infection.

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

"Child Care Facility" Any organization or business created for, and having as its major purpose, the daily care and/or education of children under the age of 7 years.

"Communicable Disease" means "Contagious Disease".

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

"Contagious Disease" - An infectious disease that can be transmitted from person to person, or animal to person.

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

"Division" - The Division of Public Health.

"Division Director" The Director of the Division of Public Health.

"Directly Observed Therapy (DOT)" an adherence-enhancing strategy in which a health care worker or other designated person watches the patient swallow each dose of medication.

"Epidemic" or "Outbreak" 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" Any person or entity who provides health care services, including, but not limited to, 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.

"**HIV Infection**" repeatedly reactive screening tests for HIV antibody (for example, enzyme immunoassay) with specific antibody identified by the use of supplemental tests such as Western Blot or immunofluorescence assay; or direct identification of virus in host tissues by virus isolation (for example, culture); or HIV antigen detection (for example p24 antigen); or a positive result on any other highly specific licensed test for HIV.

"Infectious disease" 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" 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 to non-isolated individuals.

"Medical Examiner" 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" A disease occurring in a patient in a health-care facility and in whom it was not present or incubating at the time of admission. Also known as Healthcare Associated Infection.

"Notifiable Disease" An infectious disease or condition of public health significance required to be reported to the Division of Public Health in accordance with these Rules.

"Notification" A written**, electronic,** or verbal report as required by any section of these Rules.

"Outbreak" - Refer to definition of "Epidemic".

“Post-Secondary Institution” Means and includes state universities, private colleges, technical and community colleges, vocational technical schools and hospital nursing schools.

“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, Poses a high probability of any of the following harms:
    1. A large number of deaths in the affected populations;
    2. A large number of 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 a large number of people in the affected population.

"Quarantine" 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 and who do not show signs or symptoms of contagious disease from non-quarantined individuals to prevent or limit the transmission of the disease to non-quarantined individuals.

“Resistant Organism” Any organism which traditionally was inactivated or killed by a drug but has, over time, developed mechanisms to render that drug ineffective. Also known as Multi-Drug Resistant Organism.

"Sensitive Situation" A setting, as judged 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 notifiable 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 Title 20 3132(11) of the **Delaware Code**. Sensitive situations may include, but are not limited to, schools, child-care facilities, hospitals, and other patient-care facilities, food storage, food processing establishments or food outlets.

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

"Suspect" A person or animal whose medical history and symptoms suggest that he or it may have or may be developing an infectious disease condition.

"Syndromic Surveillance" - 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 (2/1/06)

2.0 Conditions to be Reported, Timeliness and Manner of Reporting

2.1 Notifiable Diseases Reporting

The notifiable diseases specified in the Appendices to these regulations 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 to the Division of Public Health. 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 Notifiable Disease Reports

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

2.2.2 Except as otherwise provided by these regulations, reports of notifiable or other diseases or conditions required to be reported by these regulations shall contain sufficient information to contact person reporting. When available, the following information shall be reported: the name,

address, telephone number, date of birth, race, 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

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. 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

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

The Division may establish a system for electronic reporting to improve the accuracy and timeliness of reporting notifiable diseases. 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. 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

The Division may establish a state-wide 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. Those authorized to participate in syndromic surveillance must meet minimum standards for compliance and training as determined by the Division. The Director will establish what syndromes will be reported. The Director may change and/or add reportable syndromes to assure the monitoring of health events of public health importance.

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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 notifiable disease or clusters of any illness which may be of public concern, shall report such outbreaks 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, but are not limited to:

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.

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4.0 Persons and Institutions Required to Report

4.1 Health Care Providers

Reports required by Sections 2 and 3 shall be made to the Division Director or designee by any health care provider who diagnoses or suspects the existence of any disease required to be reported or by the medical examiner in such cases of that he or she 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 notifiable 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 notifiable 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 Section 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, should the disease occur in a nosocomial disease outbreak situation which 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 notifiable diseases electronically per Section 2.5 and syndromic surveillance data per Section 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 Division of Public Health Laboratory specimens or culture results for agents causing certain diseases listed in the Appendices of these regulations. 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 notifiable disease

4.3.1.2 A suspected agent of bioterrorism immediately upon when results were obtained

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

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. 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, sex, site of isolation, date of isolation and MIC/Zone diameter to the Division of Public Health. Upon request, the Division may waive the requirement for the reporting of said demographic information until such time that electronic reporting facilitates its reporting. In addition, 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 notifiable diseases electronically per Section 2.5, shall use this method of reporting.

4.4 Others

In addition to those who are required to report notifiable diseases, the following are requested and authorized to notify the Division Director or designee of the name and address of any person in his or her family, care, employ, class, jurisdiction, custody of control, who is suspected of being afflicted with a notifiable disease although no health care provider, as in Section 4.1 above, has been consulted: every parent, guardian, householder; every midwife, every superintendent, principal, teacher or counselor of a public or private school; every administrator of a public or private institution of higher learning; owner, operator, or teacher of a child-care facility; owner or manager of a dairy, restaurant, or food storage, food-processing establishment or food outlet; superintendent or manager of a public or private camp, home or institution; 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

Upon being notified of a case or suspected case of a notifiable disease or an outbreak of a notifiable disease or other disease condition in persons or animals, the Director of the Division or designee may take action as permitted in these Rules, and additionally as deemed necessary to protect the public health. 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, but shall not be limited to, confinement on a temporary basis until the patient is no longer infectious, and obligatory medical treatment in order to prevent the spread of disease in the community.

5.2 Examination of Patient

Any person suspected of being afflicted with any notifiable 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. 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 these regulations 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 Section 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. 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 one 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 which, 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 childcare facility in this case shall be effective upon written notification pursuant to Section 5.3.2.

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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 the period of time 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 himself or herself 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 request 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.

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. 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 6.1 through 6.2. 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 this Section. 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. 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. Following such isolation or quarantine, the Division shall file a petition within 24 hours. In addition, 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, 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 his or her continued isolation or quarantine. The hearing shall be held within 72 hours of receipt of such request, excluding Saturdays, Sundays and legal holidays. A request for a hearing shall not alter the order of isolation or quarantine. 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 his or her treatment and the terms and conditions of such quarantine or isolation. 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. 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 Title 16, Sections 520-532 of the **Delaware Code**. Provisions of 16 **Delaware Code**, Sections 520-532 that conflict with provisions of this section take precedence over this section.

9 DE Reg. 1188 (2/1/06)

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. For those diseases so prescribed, the most current recommendations of the federal Center's 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. For those diseases so prescribed,

the most current recommendations of the federal Center's 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. 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, but not limited to, 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 Sections 7.1.1 - 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 sections 7.1.1 - 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. 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 his/her 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 one of the vaccine preventable diseases specified in pursuant to sections 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. 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. 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, he/she 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 and all full and part-time students in such educational institutions if engaged in patient-care related curriculums (included but not limited to 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 two 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 section 6.1.10 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 Section 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 can not show evidence of immunity to measles pursuant to 6.1.10 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 and/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 this section.

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 6.1.14.2 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

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. Said prophylactic treatment shall be provided within 1 hour of birth and consist of (1) 1% silver nitrate in single-dose containers, or (2) a 1-2 centimeter ribbon of sterile ophthalmic ointment containing tetracycline (1%) or erythromycin (0.5%) in single-use tubes, or (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. 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. Reports provided under this rule shall specify the infected person's name, address, date of birth, gender and race 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 is in charge of 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. Reports provided under this rule shall specify the name, date of birth, race, 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 Section 7.3 shall be made in accordance with Section 2 of these regulations unless otherwise specified by these regulations.

7.3.2.4 All reports and notification made pursuant to this section are confidential and protected from release except under the provisions of Title 16 **Del. Code**, §710, and §711. From information received from laboratory notifications, 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 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 notifiable and 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 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 rule shall specify the infected person's name, address, date of birth, gender, mode of transmission and race 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 is in charge of 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. Reports provided under this rule shall specify the name, date of birth, race, gender and address of the person from whom the specimen was obtained, laboratory findings, including all CD4 T-lymphocyte percentage and test results and all viral load detection test results (detectable and undetectable), and the name and address of the health care provider and that of the processing clinical laboratory.

7.4.2.2.1 Reports made on the basis of an HIV test to detect antibodies shall only be made if confirmed with a Western Blot or other confirmatory test.

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

7.4.2.2.3 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 this section.

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

7.4.2.4 Reports of HIV/AIDS, required by Section 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 these regulations 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 this section are confidential and protected from release except under the provisions of 16 **Del.C.** §710, §711 and §1201-4, §1201A-4A. 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 this subchapter, 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(s) (if known), including spouses to the Division of Public Health so that the partner(s) may be notified of his or her 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 considered to be 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 Section 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 specifying the infected person's name, address, date of birth, race, 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. A report shall be telephoned into the Division of Public Health within two working days of the provision of service or laboratory finding.

7.5.2.2 Any person who is in charge of 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 two 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 two 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 two days of the occurrence.

7.5.3 Diagnostic Examinations

7.5.3.1 Any persons suspected of having infectious tuberculosis shall have a Mantoux tuberculin skin test, a chest radiograph, and laboratory examinations 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 7.5.2, health care providers shall manage persons with active TB disease by following one of three 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 his/her 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).

If the health care provider chooses 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 Hospital Acquired Infections

By January 1, 2008, hospital acquired 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 this section, the following definitions shall apply.

"Centers for Disease Control and Prevention (CDC)" An agency of the United States Department of Health and Human Services **[~~who~~ which]** 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 focuses national attention on developing and applying disease prevention and control (especially infectious diseases), environmental health, occupational safety and health, health promotion, prevention and education activities designed to improve the health of the people of the United States.

"Correctional Facility" Any health care facility operated at any Department of Correction facility in this State.

"Department" The Department of Health and Social Services

"Hospital Acquired Infection (HAI)" A localized or systemic condition that results from adverse reaction to the presence of an infectious agent(s) or its toxin(s); and that was not present or incubating at the time of admission to the hospital or the correctional facility.

"Hospital Acquired Infection Advisory Committee" A group that is appointed by the Secretary of the Department that includes one (1) infection control professional who has responsibility for infection control programs from each hospital or health care system in Delaware, four (4) infectious disease physicians with expertise in infection control, and one (1) representative from the State Division of Public Health, and the Public Health Hospital Infections Specialist responsible for collating and reporting data. The Secretary shall also appoint seven (7) 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.

"Infection Control Practitioner (ICP)" A registered nurse, physician, epidemiologist, or medical technologist who helps to prevent healthcare-acquired infections by isolating sources of infections and limiting their spread. The ICP systematically collects, analyzes and interprets health data in order to plan, implement, evaluate and disseminate appropriate public health practices. The ICP also trains healthcare staff through instruction and dissemination of information on infection control practices.

"National Healthcare Safety Network (NHSN)" An internet-based surveillance system that is **[~~voluntary and~~]** confidential. It is managed by the Division of Healthcare Quality Promotion at the CDC and used for the monitoring events associated with health care. It provides risk adjusted data to the participating facilities to analyze in order to recognize trends. Its initial focus is on infections in patients and healthcare personnel. There are plans to expand NHSN to include noninfectious events (such as process measures).

"Public Report" the report provided to the hospitals, correctional facilities and the public by the Department as set forth in **[16 Del.C.]** §1003A(b) **[~~of this title. (76 Del. Laws, c. 122, §1)~~]**.

"Secretary" The Secretary of the Department of Health and Social Services

7.6.2 Membership in NHSN

7.6.2.1 All hospitals in the State shall join the CDC's NHSN. If the NHSN is not open for enrollment to all hospitals by this date, all hospitals shall join the NHSN within 180 days after the CDC permits such enrollment.

7.6.2.2 Hospitals shall confer rights to the Department to have access to hospital-specific data contained in the NHSN database consistent with the requirements of **[~~this chapter. (76 Del. Laws, c. 122, §1)~~ 16 Del.C. Ch. 10A]**.

7.6.2.3 Hospital staff assigned to fulfill the obligations of reporting under these regulations shall be trained and shall follow the methods and procedures required by the NHSN as a condition of participation.

7.6.3 Persons and Institutions Required to Report

7.6.3.1 Physicians, who perform a clinical procedure, shall report to the ICP of the hospital where the clinical procedure was performed any hospital-acquired infection that the physician diagnosed at a follow-up appointment with the patient.

7.6.3.2 The hospital's reporting officer or his or her designee shall submit **[~~quarterly~~ monthly]** data on his or her hospital acquired infection rates to the Department through the NHSN, using the accepted CDC's NHSN definitions.

7.6.3.3 Correctional facilities shall collect data on hospital acquired infections and infections in the correctional health care facilities as determined by the Hospital Acquired Infection Advisory Committee and promulgated by the Department. They shall report this data to the Department on a monthly basis.

7.6.3.4 If the hospital 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 subsidiary and not for the other entity.

7.6.4 Reporting of Data

7.6.4.1 Hospitals shall collect data on hospital acquired infection rates related to central line-related bloodstream infections (CLBSI) in an intensive care unit (ICU) on a monthly basis.

7.6.4.2 Other hospital-acquired infection rates shall be updated by the order of the Department per determination by the Hospital Acquired Infection Advisory Committee.

7.6.4.3 Hospitals shall report hospital acquired infections pursuant to 7.6.4.1 and 7.6.4.2 to the NHSN. In making such reports, hospitals 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 Quarterly Reports

7.6.5.1 In addition to reports of data required by 7.6.4, hospitals, including the Department of Correction, shall report the following information to be included in the quarterly report issued by the Department. This background information shall be included in the Public Report.

7.6.5.1.1 For each hospital, adult and pediatric populations of each hospital, whether the hospital provides tertiary care, bed size, and specialty divisions of each hospital and whether a hospital is a teaching or a non-teaching institution shall be provided to the Department.

7.6.5.1.2 All physicians who perform clinical procedures and the hospital at which the clinical procedures were performed when a hospital-acquired infection was diagnosed at a follow-up appointment with the patient shall be included in the report. The infection control department of each hospital shall only be required to report those physician-reported infections that meet the accepted NHSN definitions. This information shall be included in the hospital reports to the Department.

7.6.5.1.3 For Department of Correction, the population census of each infirmary facility, the type of facility, the number of beds in correctional health facilities, and the types of medical care that are provided to the inmates shall be reported to the Department.

7.6.5.2 Quarterly reports shall be available to each hospital 45 days after submittal to the Department for review by the hospitals and correctional facilities. The hospitals and correctional facilities shall have 7 days to review the quarterly reports and report any changes or provide additional summary information to the Department. Following the 7-day review period, such quarterly reports shall be made available to the public at each hospital, each correctional facility, and through the Department (the "Public Report").

7.6.5.3 In addition to reports of data required by 7.6.4, hospitals, including the Department of Correction, shall report the following information. Each hospital and correctional facility shall provide a brief summary report to comment on performance improvement, changes in patient population, and risk factors. The information contained in this report shall be considered proprietary information and shall be utilized by the Department. Such information shall not be included in the quarterly report issued by the Department and shall not otherwise be disclosed to the public.

7.6.6 No hospital report or Department disclosure may contain information identifying a patient, employee or licensed health care professional in connection with a specific infection incident. **[~~(76 Del. Laws, c. 122, §1)~~ 16 Del.C. Ch. 10A]**

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

AIDS (S)
Amoebiasis
Anthrax (T)
Arboviral human infections (including West Nile Virus, Eastern Equine Encephalitis, etc.)
Babesiosis
Botulism (T)
Brucellosis (T)
Campylobacteriosis
Central line related bloodstream infections in an intensive care unit (H)
Chancroid (S)
Chickenpox (Varicella)
Chlamydia (S)
Cholera (toxigenic Vibrio cholerae 01 or 0139) (T)
Coccidioidomycosis
Creutzfeldt-Jakob Disease (T)
Cryptosporidiosis
Cyclosporiasis
Cytomegalovirus (neonatal only)
Dengue Fever (T)
Diphtheria (T)
Enterhemorrhagic E.coli including but not limited to E.coli 0157:H7 (T)
Ehrlichiosis
Encephalitis
Enterococcus species, Vancomycin resistant (A)
ESBL resistance (Extended-Spectrum B-lactamases) (A)
Foodborne Disease Outbreak (T)
Giardiasis
Glanders (T)

Gonorrhea (S)
Granuloma inguinale (S)
Guillain-Barre
Hansen's Disease (Leprosy)
Hantavirus (T)
Haemophilus influenzae, invasive
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 Infant Mortality (T)
Kawasaki Syndrome
Lead Poisoning
Legionellosis
Leptospirosis
Listeriosis
Lyme Disease
Lymphogranuloma venereum (S)
Malaria
Measles (T)
Melioidosis
Meningitis
Meningococcal Infections, all types (T)
Monkey Pox (T)
Mumps (T)
Norovirus
Nosocomial (Healthcare Associated) Disease Outbreak (T)
Pelvic Inflammatory Disease (N. gonorrhea, C. trachomatis, or unspecified) (S)
Pertussis (T)
Plague (T)
Poliomyelitis (T)
Psittacosis
Q Fever
Rabies (man and animal) (T)
Reye Syndrome
Rheumatic Fever
Ricin Toxin (T)
Rickettsial Disease
Rocky Mountain Spotted Fever

Rubella (including congenital which is rapidly reportable)
Rubella, congenital (T)
Salmonellosis
Severe Acute Respiratory Syndrome (SARS) (T)
Shigatoxin Production
Shigellosis
Silicosis
Smallpox (T)
Staphylococcal Enterotoxin (T)
Staphylococcal aureus, Methicillin Resistant (MRSA) (A)
Staphylococcal aureus, Vancomycin Intermediate or Resistant (VISA, VRSA) (T) (A)
Streptococcal Disease, invasive group A or B (T)
Streptococcus pneumoniae, invasive (sensitive and resistant) (A)
Syphilis (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
Vibrio, non-cholera
Viral Hemorrhagic Fevers (T)
Waterborne Disease Outbreaks (T)
Yellow Fever (T)
Yersiniosis
(T) - report by rapid means (telephone, fax or other electronic means)
(S) - sexually transmitted disease, report required within 24 hours
(A) - Drug Resistant Organisms required to be reported within 48 hours
(H) – Hospital Acquired Infection
Others - report required within 48 hours

9 DE Reg. 1188 (2/1/06)

8.0 Preparation for Burial.

See 16 **Del.C.** Ch. 31 and Department of Health and Social Services regulations promulgated thereunder, entitled "Regulations Concerning Care and Transportation of the Dead".

9 DE Reg. 1188 (2/1/06)

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 "Regulations Concerning Care and Transportation of the Dead", Section 10 ("Disposition of Amputated Parts of Human Bodies").

9 DE Reg. 1188 (2/1/06)

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 (2/1/06)

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

11.1 Definitions

For the purposes of this section, the following definitions shall apply.

"Emergency medical care provider" 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 and/or provides pre-hospital emergency medical service.

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

"Standard precautions" 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 blood, body fluids, secretions, and excretions of care providers use appropriate barrier precautions to prevent exposure to blood and body fluids of all patients at all times.

11.2 Standard Precautions

11.2.1 Didactic Instruction

Education and training with respect to universal 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 person(s) being trained. Training shall include, but not be limited to, 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 The proper techniques of disinfection and clean-up 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 The 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 which may be incurred by an emergency medical care provider.

11.2.2 Practical or Laboratory Instruction

Practical sessions addressing the field application of the above didactic instruction must be part of the curriculum. The practical sessions shall provide a means of hands-on experience and training in the proper use of personal protective equipment, hand-washing disinfection, clean-up of infectious spills, handling and disposal of contaminated sharps, and the proper completion of reporting forms.

1.1.2.3 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 10.2.1 and 10.2.2.

11.3 Communicable Diseases

11.3.1 Communicable Disease Defined

For the purposes of Section 11 only, exposure to patients infected with the following communicable disease agents shall warrant notification to an emergency medical care provider pursuant to this section:

Human Immunodeficiency Virus (HIV)

Hepatitis B Virus

Hepatitis C Virus

Meningococcal disease

Haemophilus influenzae

Measles

Tuberculosis

Uncommon or rare pathogens

11.3.2 Infection Defined

For the purposes of Section 11 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 Air-borne and droplet spread pathogens

11.3.2.2.1 Meningococcal disease -compatible clinical findings and laboratory confirmation through isolation of Neisseria meningitids 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 one of the following methods: (1) presence of the measles virus from a clinical specimen, or (2) four-fold rise in measles antibody level by any standard serologic assay, or (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 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 Air-borne and droplet spread pathogens

Exposure of an emergency medical care provider to a patient infected with an air-borne or droplet spread pathogen as defined in 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 one 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 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(s) 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 these regulations.

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 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 Air-borne and droplet spread Pathogens

11.5.1 Notwithstanding any requirement of 11.4.3, a receiving medical facility must make notification when an emergency medical care provider has been exposed to an air-borne or droplet spread communicable disease pursuant to 11.3.2.2 and 11.3.3.2. Such notification shall occur as soon as possible but not more that 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 air-borne 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 10.4.3, 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 10.4.1 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;

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 Section 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;

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 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

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 11.4.1. 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

If, within the 30-day limitation defined in 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. The second receiving medical facility must make notification to the officer designated pursuant to 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 these regulations.

11.9 Death of Patient

If, within the 30-day limitation defined in 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. 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 these regulations.

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 these regulations shall be used solely for the purposes of complying with these regulations and are otherwise confidential.

9 DE Reg. 1188 (2/1/06)

APPENDIX I

State of Delaware - List of Notifiable Diseases/Conditions

Table 1: State of Delaware

List of Notifiable Diseases/Conditions	
AIDS (S)	Amoebiasis
Anthrax (T)	Arboviral human infections (including West Nile Virus, Eastern Equine Encephalitis, etc.)
Babesiosis	Botulism (T)
Brucellosis (T)	Campylobacteriosis
Chancroid (S)	Chickenpox (Varicella)
Chlamydia (S)	Cholera (toxigenic Vibrio cholerae 01 or 0139) (T)
Coccidioidomycosis	Creutzfeldt-Jakob Disease (T)
Cryptosporidiosis	Cyclosporiasis
Dengue Fever (T)	Diphtheria (T)
Enterhemorrhagic E.coli including but not limited to E.coli 0157:H7 (T)	Ehrlichiosis
Encephalitis	Enterococcus species, Vancomycin resistant (A)
ESBL resistance (Extended-Spectrum ß-lactamases) (A)Cytomegalovirus (neonatal only)	Foodborne Disease Outbreak (T)
Giardiasis	Glanders (T)
Gonorrhea (S)	Granuloma inguinale (S)
Guillain-Barre	Hantavirus (T)
Haemophilus influenzae, invasive	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 Infant Mortality (T)	Kawasaki Syndrome
Lead Poisoning	Legionellosis
Leptospirosis	Listeriosis
Lyme Disease	Lymphogranuloma venereum (S)
Malaria	Measles (T)
Melioidosis	Meningitis

Table 1: State of Delaware

List of Notifiable Diseases/Conditions	
Meningococcal Infections, all types (T)	Monkey Pox (T)
Mumps (T)	Norovirus
Nosocomial (Healthcare Associated) Disease Outbreak (T)	Pelvic Inflammatory Disease (N. gonorrhea, C. trachomatis, or unspecified) (S)
Pertussis (T)	Plague (T)
Poliomyelitis (T)	Psittacosis
Q Fever	Rabies (man and animal) (T)
Reye Syndrome	Rheumatic Fever
Ricin Toxin (T)	Rickettsial Disease
Rocky Mountain Spotted Fever	Rubella (including congenital which is rapidly reportable)
Salmonellosis	Severe Acute Respiratory Syndrome (SARS) (T)
Shigatoxin Production	Shigellosis
Silicosis	Smallpox (T)
Staphylococcal Enterotoxin (T)	Staphylococcal aureus, Methicillin Resistant (MRSA) (A)
Staphylococcal aureus, Vancomycin Intermediate or Resistant (VISA, VRSA) (T) (A)	Streptococcal Disease, invasive group A or B (T)
Streptococcus pneumoniae, invasive (sensitive and resistant) (A)	Syphilis (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	Vibrio, non-cholera
Viral Hemorrhagic Fevers (T)	Waterborne Disease Outbreaks (T)
Yellow Fever (T)	Yersiniosis

(T) - report by rapid means (telephone, fax or other electronic means)

(S) - sexually transmitted disease, report required within 24 hours

(A) - Drug Resistant Organisms required to be reported within 48 hours

Others - report required within 48 hours

9 DE Reg. 1188 (2/1/06)

APPENDIX II

Organisms and Samples to be sent to the Division of Public Health Laboratory

1. Clinical or hospital laboratories, or other facilities, that presumptively identify or are unable to rule out the following organisms shall send an isolate or specimen to the Delaware Public Health Laboratory for testing immediately:

Brucella species

Burkholderia mallei

Burkholderia pseudomallei
Clostridium botulinum
Franciscella tularensis
Yersinia pestis
Bacillus anthracis

2. Any environmental sample deemed as credible threats for harboring a toxin or a biological agent of terrorism shall be sent to the Delaware Public Health Laboratory for testing immediately upon identification:

3. Clinical specimens from patients potentially exposed to a chemical agent of terrorism shall be sent to the Public Health Laboratory for testing immediately upon identification.

4. Clinical specimens from suspect human cases of the following infections shall be sent to the Delaware Public Health Laboratory for testing immediately upon identification

Monkeypox
Variola (Smallpox)
Vaccinia
SARS

5. The following isolates from humans shall be sent to the Delaware Public Health Laboratory for testing within 24 hours of identification:

Enterohemorrhagic E. coli, including 0157
Haemophilus influenzae, sterile sites
Mycobaterium tuberculosis
Listeria monocytogenes
Neisseria meningitidis, sterile sites
Salmonella species
Shigella species
Streptococcus pneumoniae, sterile sites, Penicillin resistant
Staphylococcus aureus, sterile sites, Methicillin resistant
Staphylococcus aureus, Vancomycin intermediate or resistant (VISA, VRSA)
Vancomycin resistant Enterococci, (VRE) sterile series
Vibrio cholerae and Non-cholerae

9 DE Reg. 1188 (2/1/06)

12 DE Reg. 1418 (05/01/09) (Final)