DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
Statutory Authority: 16 Delaware Code, Section 122(3).0 (16 Del.C. §122(3).0) 16 DE Admin. Code 4202

FINAL

ORDER

4202 Control of Communicable and Other Disease Conditions

Nature of the Proceedings

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt amendments to the State of Delaware Regulations for the Control of Communicable and Other Disease Conditions. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code,** Sections 122; 128; 129; 504; 505; 507; 702 and 707.

On December 1, 2005 (Volume 9, Issue 6), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by January 3, 2006, after which time DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written 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 for the Control of Contagious and Other Disease Conditions are adopted and shall become effective February 10, 2006, after publication of the final regulation in the *Delaware Register of Regulations.*

Vincent P. Meconi, Secretary, January 13, 2006

Summary of Evidence

In accordance with Delaware Law, public notices regarding proposed amendments to the Department of Health and Social Services (DHSS) Regulations for the Control of Communicable and Other Disease Conditions were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (December 1, 2005 through January 3, 2006). Entities offering written comments included:

- State Council for Persons with Disabilities (SCPD)
- Bayhealth Medical Center Infection Control Department
- Delaware Health Care Facilities Association
- Christiana Care Health System Infection Control
- Delaware Regional APIC
- Nemours duPont Hospital for Children Infection Control
- Blood Bank of Delmarva

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

Multiple statutory provisions in Title 16 (Chapters 5 and 7) and Title 20 (Chapter 31) covering reporting of communicable diseases, voluntary and involuntary treatment, and due process procedures sometimes overlap and are

not uniformly consistent. There are multiple provisions which indicate that the Title 20 (public health emergencies) provisions supersede any inconsistent provisions in Title 16. See, e.g., Title 16 **Del.C.** §§505(c), 508(g), and 532. This "loose" integration of statutes undermines the development of a single set of regulations.

Agency Response: The agency is not authorized to change statute. A purpose of the proposed regulations is to provide more consistency between the regulations and the statute.

The definition of "epidemic or outbreak" merits review. Literally, the declaration of a state of emergency due to a widespread illness cannot be considered an epidemic or outbreak. It is recognized that Title 20, **Del.C**. §§3137, 3138, and 3140 grant certain emergency powers in the event of a state of emergency. However, Title 20 does not contain mandatory reporting provisions. By including a "state of emergency" in the definition of "epidemic or outbreak", the regulations would reinforce the mandate in Section 3.0 that health care providers report "outbreaks", "clusters of illness", and all cases related to a health emergency. Alternatively, perhaps a definition of "public health emergency" (Section 3.2) could be included which would include diseases/conditions identified in a state of emergency declaration.

Agency Response: The agency will amend the definition of "Epidemic" or "Outbreak" and add the definition of public health emergency to the regulation.

Section 4.4: This section authorizes, but does not require, primarily non-medical persons to report notifiable diseases. The preface indicates that the section is intended to supplement the mandatory reporting provisions in the regulations. The proposed revision in this section deletes "every nurse", ostensibly since nurses are within the definition of "health care provider" who would be subject to mandatory reporting. However, the term "dentist" is retained in Section 4.4 despite the inclusion of dentists in the definition of "health care provider". The term "dentist" should logically be deleted from Section 4.4.

Agency Response: The agency will delete "dentist" from Section 4.4

There is some inconsistency between Sections 3.1 and 3.2.1 and Section 4.4. Sections 3.1 and 3.2.1 require any person identified in Section 4 to report knowledge of a notifiable disease. In contrast, Section 4.4 literally makes such reporting by many persons optional, i.e., reporting is "requested and authorized" but not required. This creates ambiguity in the regulatory scheme.

Agency Response: The agency will amend the regulation such that Section 3.1 reads "Any health care provider having knowledge of any outbreak…shall report…"

The term "engaged in sensitive situations" in Section 5.3.1 is grammatically odd. How does one engage in a setting? DPH may wish to consider alternative terminology.

Agency Response: The phrase "engage in sensitive situations" has been part of the regulations since their inception. Experience suggests that it appears to be well understood.

The Section 6.0 quarantine and isolation due process procedures are derived from Title 20 Del.C. §3136 which is only applicable to public health emergencies. The Code directs that DPH regulations extend similar rights to persons quarantined under Title 16 Del.C. §§505-506. However, there are separate due process procedures for quarantine for sexually transmitted diseases which contemplates J.P. Court proceedings [Title 16 Del.C. §§704-705]. There are also separate due process standards applicable to quarantine for tuberculosis [Title 16 Del.C. §§526 and 529]. The proposed regulations make no such distinctions and ostensibly apply one set of due process standards to all quarantines.

Agency Response: The agency will add Section 6.10 to the regulation to address additional due process rights.

Section 11.1: Recommend Universal precautions be changed to Standard Precautions throughout the document and defined per CDC. Universal Precautions addressed only bloodborne Pathogens. Standard Precautions is designed to reduce the transmission risks of all communicable diseases.

Agency Response: The agency will change all references to "universal precautions to "standard precautions."

Section 11.3.2.2: Air-borne needs to be either defined in the data dictionary or changed. The term is confusing with the CDC list of air-borne organisms. For example, meningitis from N. meningitides or Haemophilus influenzae is considered Droplet precautions per CDC, not air-borne. If the term air-borne is used to describe "organisms that

travel by air", that should be defined in the data dictionary to prevent confusion.

Agency Response: The agency will change all references to "air-borne" to "air-borne and droplet spread."

Appendix II Organisms and Samples to be sent to the Division of Public Health Laboratory. Sending isolates of Staphylococcus aureus, sterile sites, Methicillin resistant, and Vancomycin resistant Enterococci VRE will significantly increase the workload for all of the clinical laboratories around the state and the Delaware State Public Health Lab without improving care to our population. CCHS disagrees with the utility of sending those isolates and demographic data. What is being done with the information, especially the patient demographics? Can the requirement for demographic information on the resistant organisms be delayed until DERSS is fully operational and can download this information automatically? Can we continue with our current method of reporting resistant organisms?

Agency Response: The agency will revise the proposed regulations so as to not require sending isolates to the agency laboratory for: "staphylococcus aureus, sterile sites, Methicllin resistant," and "Vancomycin resistant Enterococci (VRE) sterile sites." The agency will provide a provision that reporting of demographic information for antimicrobial resistant organisms can be delayed until such information can be reported though electronic means.

Under definitions, add Isolation Precautions, as defined by the CDC Isolation Guideline: Airborne Precautions; Droplet Precautions; and, Contact Precautions. Also include types of Personal Protective Equipment (PPE) needed to work safely within each type of Isolation Precaution.

Agency Response: The agency considers the regulation of hospital infection control to be beyond the scope of these regulations.

Replace the old terminology of 'nosocomial' with Healthcare-Associated Infection (HAI) as defined by the CDC Isolation Guideline.

Agency Response: The agency will include this terminology in the definition of nosocomial infection.

In the definition of Contagious Diseases add 'vector-borne' since infections such as Lyme Disease, Rocky Mountain Spotted Fever, and Malaria are considered Notifiable.

Agency Response: The agency considers this to be included in "animal-to-person," which is part of the definition of contagious diseases.

In the definition of Bloodborne Pathogens, add 'Tissue, CSF, Synovial fluid, Peritoneal fluid, Pericardial fluid, and Amniotic fluid'.

Agency Response: The agency is assuming that this comment pertains to Section 11.3.3.1. The agency will add the suggested language.

In reporting of Varicella, is Infection Control required to report 'confirmed cases' only? If clinically diagnosed cases are to be included, we will need to create processes for information capture on the Hospital side (likely, a manual process).

Agency Response: Section 2.1 states that the "occurrence or suspected occurrence" of notifiable diseases listed in the Appendix shall be reported. Therefore non-confirmed varicella shall be reported if that diagnosis is clinically suspected.

Under definitions 'Resistant Organism' is now referred to as 'Multi-Drug Resistant Organism (MDRO)'.

Agency Response: The agency will include this terminology in the definition of resistant organism.

Section 11.10: Under 'Testing of Patients for Infection', will this prevent testing a source patient when an exposure event occurs to a medical care provider (Post Exposure Testing for HIV and Hepatitis)? Our understanding is *Delaware Law,* Chapter 12 does allow for source patient testing when related to an exposure event. Can this be clarified?

Agency Response: Section 11.10 pertains only to the provisions of Section 11.0 (Notification of Emergency Medical Care Providers of Exposure to Communicable Diseases" and does not explicitly prohibit patient testing (it just does not authorize it). Title 16, Chapter 12 of the **Delaware Code** still applies.

Appendix II Organisms and Samples to be sent to the Division of Public Health Laboratory: Should ESBLs isolated from sterile samples also be sent to the DPHL?

Agency Response: The agency reviewed this comment in the context of other comments made on sending

antimicrobial resistant isolates to the Division's laboratory. The agency concluded that the inconvenience and time necessary to send ESBL does not justify the potential for disease control.

Enteric Pathogen infections in Health Care Personnel – the CDC Guidelines for Health Care Personnel allows return to work after symptoms resolve, unless local Regulations require exclusion from duty. What is the DPH reference for Enteric infection Regulation? The citation appears to be missing..

Agency Response: The agency is not clear about what section of the proposed regulation is being commented upon. A hospital employee with an enteric infection would be a matter of hospital infection control and generally outside the scope of these regulations. However, the agency can provide recommendations addressing this situation.

The document language does not make clear the level of Hospital participation with DERSS. There is no clarity regarding 'automatic electronic transfer' of epidemiologically-important information from Hospital to DERSS. Automatic electronic transfer addresses accuracy and timeliness of the information. It also addresses the timeliness of Emergency Room Syndromic Surveillance Reporting, which may be 24-72 hours behind when using the current reporting mechanisms.

Agency Response: The regulations will be clarified to indicate that the agency will provide technical specifications, and that the hospital must make a good faith effort to conform to such specifications.

Section 3.0 Report of Outbreaks: The regulation never stipulates what constitutes an outbreak, i.e. 3 cases on one wing or 3% of the whole house-wide population. It indicates an increase above the expected number, however, no specific guidance for what that average number is has been supplied. The section is extremely vague and does not include disease specific guidelines, i.e. one case of active TB = an outbreak, 3 cases of gastrointestinal illness on the same unit or 3% of the facility population.

Agency Response: The definition states "clearly in excess of normal expectancy." The agency asserts that this definition is sufficiently specific.

Section 4.0 Persons/Institutions required to report: What is the definition of "unattended death" and why is it reported by the medical examiner? What about extended care facilities, group homes, etc, where a medical examiner is not usually present?

Agency Response: The regulations will be revised to make clear that the medical examiner will report the occurrence of a notifiable disease for all cases he or she examines.

Section 4.3.3 Reporting of antibiotic resistant organisms: Is the lab required to report first, and how does the care facility/hospital know if it has been reported? Who is required to report this? One organism could be reported multiple times if this section is followed. Why are they reporting every case? MDRO's are becoming endemic and usually the only time they are reported is in an outbreak situation or if a new genetic shift/drift is identified.

Agency Response: See previous comment and response on this Section. The facility can develop their own procedures to report.

Section 5.3 Sensitive situations: What does this mean? Reference to definition in "Part II I" is not in the document. The definition does not include specific examples, which makes following very difficult. Too vague and needs more information.

Agency Response: The phrase is defined in Section 1.0. The inaccurate reference to Part II I will be changed.

Section 6.0 Quarantine and Isolation: There is no difference in the proposed definitions, so one term needs to be used only. It is assumed this section is not referring to MDRO's, but is referring to epidemiologically significant infections, i.e. E.bola, Avian flu, SARS, etc. By current guidelines we "isolate the organism", not the patient, for illnesses other than those types. Section 6.3.2 makes absolutely no sense, as it states "isolated individuals must be confined separately from quarantined individuals." What is the difference? The term Isolation applies to Standard and Transmission based precautions, and in this case, is different from quarantine, but is referenced inappropriately in this section as being interchangeable.

Agency Response: The terms are separately defined in Section 1.0. Quarantine refers to exposed, well persons who may be infected. Isolation refers to ill, infected persons. Section 6.3.2 indicates that quarantined persons must be confined separately from isolated patients. Isolation and quarantine, under this regulation, may be implemented at the

discretion of the agency in the community or in a hospital. However, unless so ordered by the agency, it does not supersede hospital isolation procedures. The agency asserts that this section is sufficiently clear.

Section 7.5.3.1 Diagnostic examination (TB): Why would gastric contents be considered for screening? Extra pulmonary cases of TB are not transmissible person to person, so this section should focus on screening and diagnosis of laryngeal or pulmonary TB only. Why doesn't this section speak to admission screening and annual symptom surveillance for inpatients? There is no clear guidelines how to screen, only dealing with active disease. Is there a separate regulation/guideline for this?

Agency Response: The reporting of gastric contents would be required for diagnosis only at the discretion of the agency. The agency asserts that the section appropriately requires diagnosis of extra-pulmonary TB. Even though it is not communicable, it contributes to understanding of the epidemiology of TB in Delaware and it may indicate the need to investigate the source of the extra-pulmonary TB for adequate disease control. However, as the comment indicates, extra-pulmonary TB is usually not infections. Therefore the word "infectious" will be stricken from 7.5.3.1. Regulation of admission screening and annual symptom surveillance for inpatients is a matter hospital infection control procedures and is beyond the scope of these regulations.

Section 11.1 Definitions: The term "Universal Precautions" must be stricken from the regulation, as it has not existed since November of 1996. Standard and Transmission based Precautions is the correct verbiage and the section must reflect this changes made in the 1996 HICPAC guidelines. Barrier precautions not required at all times, the verbiage reads "as necessary". One does not use full PPE to walk into a patient room any longer. The guidelines are very clear, including the grid fro what type/how often precautions are needed. Please review the documents to update the regulation.

Agency Response: "Standard precautions" will replace "universal precautions." Because the regulations use the word "appropriate" barrier precautions, the agency asserts that the section is sufficiently clear.

Section 11.2.1.6 Exposure to communicable disease: Use of safety sharps, unless a reasonable alternative is not available needs to be included, yet is not mentioned. This is an OSHA mandate.

Agency Response: The words, "and safety sharps" will be added.

Section 11.3.3.2.1 Airborne pathogens: Varicella should be but is not mentioned in this section and it is an airborne pathogen. Meningococcal disease and H. flu are not spread by airborne means, but by large droplet nuclei, which fall under the category of Droplet Precautions, not Airborne. Airborne illnesses require N95 masks/respirators prior to entering a resident's room. Droplet Precautions require a surgical mask within 3 feet of the infected individual. Therefore, they are different processes and entities.

Agency Response: See previous comment and response on this Section. The agency will conduct a more extensive review of this section in the near future.

Section 11.10 Testing of Patients for Infection: Again, screening for TB needs to be addressed. Why are there no provisions for post acute/non hospital settings?

Agency Response: The Section does not specifically authorize testing (including TB), but does not prevent it. Section 1.1 defines receiving medical facility as a hospital or similar facility who receives a patient for continued medical care. This definition would include post acute/non hospital settings.

It is unclear as to the significance of sharing specimens or culture results for agents causing certain diseases listed. The question is what exactly are they going to do with such results, or specimens? There isn't a problem referring agents of bioterrism (the document should define what those are), or even Vanco I/R Stpah aureus, but routine MRSA's, or Strep pneumonias's don't seem significant. We are confident in our abilities to accurately detect these organisms, thus it is not clear as to why they are wanted.

Agency Response: See previous comments and responses on antimicrobial resistant organisms.

It looks like a version of our antibiogram (pg 6) "In addition, the number of susceptible and non-susceptible isolates…shall be reported monthly…". We pull our antibiogram yearly, not quite sure why this information would need to be reported monthly.

Agency Response: The data that is requested monthly is only the total number of susceptible and non-susceptible isolates by organism. No personal identifying, susceptibility patterns, or other information is required on this report denominator data that is utilized to determine incidence and prevalence rates.

Section 1.0 Definitions: A better definition of Resistant Organism would be necessary.

Agency Response: Since no specific concern about the definition was submitted with this comment, the agency will leave the definition as is. However, based on another comment, the agency updated the definition of Resistant Organism by adding Multi-Drug Resistant Organism to the definition.

Under Sections 2.2 and 7.3.2.3, there is a concern about 48 hour reporting, since IC is not a 24 hour department and generally does the reporting. We would recommend 3 or 4 "working days" as better time/terminology.

Agency Response: The agency's mission would be impaired by further delaying disease reports. The development of electronic reporting should make it easier for hospitals and laboratories to report timely. Section 7.3.2.3 pertains to STD. Title 16, Chapter 702 of the **Delaware Code** requires reports of STD to be made within one working day.

Under Section 4.2.2 took away the definition of practitioner in 4.1, but referred to it in this section.

Agency Response: The phrase "attending practitioner" will be replaced by "health care provider" in Section 4.2.2

Under 4.3.3 defining antibiotic resistant organisms, since IC reports electronically will the labs be able to interface, the requirements to report MIC/Zone. There may not be enough space in the current DERSS 100 character field. SSN is not listed here as a reporting requirement. Can the total number of susceptible and non-susceptible isolated be entered on the line? Referral to the "reporting officer" is mentioned. It would be beneficial if the state could provide the reporting officer for a facility, or even one per county.

Agency Response: The concerns are procedural in nature and not a matter of regulation. The agency is working on plans to accommodate reports. Section 4.2 refers to a reporting officer who shall be appointed by each hospital. Reporting officers are not provided by the state.

In Section 4.4, jail and prison are used interchangeably. Are they the same?

Agency Response: The word "jail" in Section 4.4 will be changed to "prison."

Under Section 7.4.2.4, we usually call HIV with the report, will that continue to be acceptable?

Agency Response: As specified in this Section, other means of reporting are permitted upon approval of the Division.

Section 11.4.1, requires every employer of an EMS provider and every organization that supervises volunteer EMS providers to register a designated officer. Under the current system, there does not seem to be an ongoing maintenance of this system, and we would recommend including how this should be done and who is responsible for overseeing this so that the Medical Facility can notify the appropriate designated officer as per the form that was approved by the State Board of Health. Ongoing education with these designated officers should also be addressed in this document.

Agency Response: The agency will conduct a thorough review of Section 11.0 in the near future.

Under the new listing of reportable organisms, what is the significance of reporting CMV. We think at best we should only be reporting neonatal infections with CMV. Additionally, we also have concern over the requirement for reporting ESBL resistance. We don't know the significance and potentially would be talking about a large number of reports. The other issue we have is why is it important that MRSA and VRE be reported in 48 hours? A great percentage of these isolates are colonization not infection and are not significant enough to require 48 hour reporting. It would be almost impossible to report all STD's within 24 hours.

Agency Response: The agency will change the proposed reportable disease list to include only neonatal CMV. Reporting of ESBL, as well as other antimicrobial organisms is necessary for the agency to understand its epidemiology in Delaware. The agency will include a provision that the requirement to report demographic information for antibiotic resistant organisms may be delayed until electronic reporting mechanisms are in place for this purpose. The time frame for STD reporting is specified in law (Title 16, Chapter 702). The agency is not authorized to change this requirement..

Clinical labs will be unable to meet 24 hour deadline to send isolates to the Public Health Lab. 3 to 4 working

days would be more realistic. What forms need to be submitted with the isolates since they go to the lab and not the epidemiology section? Also, will the state courier service be available all of this time?

Agency Response: The agency will be unable to effectively fulfill its disease control mission if isolates are delayed 3 or 4 days. Forms and courier service questions should be directed to the Division of Public Health Laboratory and are not a matter of regulation.

Under the definition section if the word "carriers" is used, it should be co-jointly with the terminology colonization.

Agency Response: A carrier may be infected as well as colonized with a pathogen. The definition is consistent with "Control of Communicable Disease Manual", 18th edition, published by the American Public Health Association.

Section 1.0 Definitions: "HIV Infection" to include HIV NAT (Nucleic Acid Testing) as an option.

Agency Response: The definition in Section 1.0 provides examples only. HIV NAT would therefore be included.

Section 2.0, subsection 2.2.1, specifies that reports pursuant to this subsection shall be made electronically, telephonically, 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. The Blood Bank of Delmarva's policy is to notify the office of Division of Public Health immediately after mailing a letter to the donor regarding his/her confirming test results, which usually occurs within 72 hours from receipt of confirmatory test results.

Agency Response: The agency cannot effectively fulfill its mission for disease control without timely reports. The Blood Bank has the choice of notifying the donor sooner, or notifying the Division first.

Section 7.3, subsection 7.3.2.2 states that a donor's race and the name of the physician to be included in the report submitted to the Division of Public Health. The Blood Bank of Delmarva does not document the donor's race and his/her physician's name.

Agency Response: Section 2.2.2 indicates that such information is only required when available.

Section 7.4, subsection 7.4.2.2 states that the blood bank has to include the race of the donor and laboratory findings including all CD4 T-lymphocytes percentage and test results and viral load detection test results (detectable and non detectable), and the name and address of the health care provider and that of the processing laboratory. The Blood Bank of Delmarva does not document the donor's race and his/her healthcare provider's name. The CDC T-lymphocyte and viral load detection test results are not available to the Blood Bank of Delmarva, Inc., these results may be available to the donor's physician or the clinic that conducts diagnostic testing recommended by the donor's physician.

Agency Response: Section 2.2.2 indicates that such information is only required when available.

Section 7.4, subsection 7.4.2.4 states that reports of HIV/AIDS shall be routed to the Division of Public Health office with 48 hours of diagnosis or treatment. The Blood Bank of Delmarva, Inc., only tests a donor's sample for the presence of the virus and anti-bodies, the diagnostic test for HIV/AIDS is performed by the donor's physician.

Agency Response: The words "positive test" will be added to Section 7.4 to clarify the intent

Appendix I to include West Nile Virus disease.

Agency Response: West Nile Virus is an arbovirus, which is reportable. Appendix I will be modified to make this clear.

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

The public comment period was open from December 1, 2005 to January 3, 2006.

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~~ Contagious] and Other Disease Conditions

~~1.0 Applicable Codes~~

~~These regulations are adopted by the Department of Health & Social Services pursuant to 16 **Del. C.** §122(1), (2), (3) (a and j), (4), (5); §128; §129; §151; §503; §504; §505; §507; §508; §702; §706 and 707. These regulations were originally adopted on August 2, 1984 effective September 1, 1984**,** and subsequently amended.~~

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 an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly, through an intermediate plant or animal host, vector, or the inanimate environment~~ 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.**[~~, but not upon declaration of a state of emergency due to such illness of similar nature.~~]**

"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 ~~communicable~~ 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" ~~An official order that limits the freedom of movement and actions of persons or animals in order to prevent the spread of notifiable disease or other disease condition. The Division Director or designee shall determine which persons or animals are subject to quarantine and shall issue appropriate instructions~~ 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 **[~~to~~]** 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 a**[n ~~communicable~~ 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.

2.0 ~~Notifiable Diseases or Conditions to be Reported~~ 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. ~~Such reports shall be made within 48 hours of recognition except as otherwise provided in these regulations. Reports shall be made by telephone or in writing except for certain specified diseases as indicated by a (T) which shall be reported immediately by telephone. Certain diseases are reportable in number only and are indicated by an (N).~~ 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.

3.0 Report of Outbreaks and Potential Causes of a Public Health Emergency

3.1 Outbreaks

[~~A health care provider or any other person identified in Section 4~~ 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.

4.0 ~~Reporting of Notifiable Diseases~~ Persons and Institutions Required to Report

~~4.1 Attending Practitioners~~

~~Reports required by Sections 1 and 2 shall be made to the Division Director or designee by any attending practitioner, licensed or otherwise permitted in Delaware to practice medicine, osteopathic medicine, chiropractic, naturopathy, or veterinary medicine, who diagnoses or suspects the existence of any disease on the notifiable disease list or by the medical examiner in cases of unattended deaths.~~

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 **[~~unattended deaths~~ 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.

~~3.3.2 Such case reports shall be made to the Division Director or designee within 48 hours of recognition or suspicion, except as otherwise provided in these regulations.~~

4.2.2 Reporting of a case or suspect case of a notifiable disease by a hospital fulfills the requirements of the **[~~attending practitioner~~ 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 **[~~authorized~~ 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 ~~microbiologic~~ 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 ~~to the Division of Public Health within 48 hours of when the results were obtained or as soon as possible, except as otherwise provided in these regulations~~.

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.

~~3.4.3 Laboratories identifying salmonella or shigella organisms in the stool specimens shall forward cultures of these organisms or the stool specimens themselves to the Public Health Laboratory for confirmation and serotyping.~~

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 ~~H~~ 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 nurse,~~ **[~~every dentist~~]**, 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, **[~~jail~~ prison]**, or juvenile detention center.

~~3.5 Confidentiality~~

~~Information identifying persons or institutions submitted in reports required in Sections 3.1 - 3.4 shall be held confidential to the extent permitted by law.~~

~~3.6 Information in Reports~~

~~Information included in reports required in Sections 3.1-3.4 shall contain sufficient information to contact the patient and/or the patient's attending physician. When available, 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 attending physician; and any pertinent laboratory information, shall be provided.~~

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 ~~communicable~~ contagious disease or suspected of being infected with a ~~communicable~~ contagious disease shall engage in sensitive situations as defined in **[~~Part II~~ 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 ~~communicable~~ 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 ~~communicable~~ 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 ~~communicable~~ 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 ~~unusual~~ 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 **[~~communicable~~ 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.

~~**5.0 Quarantine**~~

~~5.1 Establishment~~

~~When quarantine of humans is required for the control of any notifiable disease or other disease or condition, the Division Director or designee shall have the authority to initiate procedures to establish a quarantine.~~

~~5.2 Requirements~~

~~5.2.1 The Division Director or designee shall ensure that provisions are made for proper observations of such quarantined persons as frequently as necessary during the quarantine period.~~

~~5.2.2 Quarantine orders shall be in effect for a time period in accord with accepted public health practice.~~

~~5.3 Transportation~~

~~5.3.1 Transportation or removal of quarantined persons may be made only with prior approval of the Division Director or designee.~~

~~5.3.2 Transportation or removal of quarantined persons shall be made in accordance with orders issued by the Division Director or designee.~~

~~5.3.3 Quarantine shall be resumed immediately upon arrival of quarantined person at point of destination for the period of time in accord with accepted public health practices.~~

~~5.4 Disinfection~~

~~5.4.1 Concurrent disinfection is required of infectious or potentially infectious secretions or excretions of any quarantined 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.~~

~~5.4.2 Disinfection shall also be carried out at the termination of the period of quarantine and shall be applied to the quarter vacated. The disinfection procedures shall be as approved by the Division Director or designee.~~

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.]

7.0 Control of Specific [~~Communicable~~ 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 l4 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 l4 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 7.1.14.2 discloses information from the immunization registry for any other purpose, it is an unauthorized release and such person may be subject to civil and criminal penalty.

7.2 Ophthalmia Neonatorum

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 list**[s]** 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 ~~physician or any other licensed~~ health care provider ~~professional~~ 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. ~~Unless reportable in number only as specified in Appendix I,~~ 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. ~~Unless reportable in number only as specified in Appendix I,~~ Reports provided under this rule shall specify the name, date of birth, race, gender and address of the person**[~~s~~]** 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 ~~this~~ Section 7.3 shall be made in accordance with Section 2 of these regulations unless otherwise specified by these regulations. ~~for STD's designated with the letter "T" in Appendix I shall be made by telephone, fax, or other rapid electronic means within 1 working day. Reports required by this Section for STD's designated with the letter "N" in Appendix I shall be made at the request of the Division of Public Health, in number only, and in demographic categories specified by the Division of Public Health. All other reports required by this Section for STD's listed in Appendix I shall be placed into the United States~~

~~mail, faxed, telephoned, or otherwise routed to the Division of Public Health within one working day of diagnosis, suspicion, or treatment.~~

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.C.** §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 ~~infection~~ 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

[~~7.4.1.3~~] Control and Prevention case definition of AIDS

7.4.1.**[~~4~~3]** A positive confirmed result of any test approved and indicative of the presence of HIV.

7.4.1.**[~~5~~4]** All CD4 T-lymphocyte percentage and test results and all viral load detection test results (detectable and undetectable)

7.4.1.**[~~6~~5]** A perinatal exposure of a newborn to HIV.

~~6.4.1 Reporting HIV Infection~~

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

7.4.2.1 A ~~physician or any other licensed health care professional~~ 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 ~~licensed health care professional~~ 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 ~~physician~~ 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.

~~6.4.2.3 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.~~

~~6.4.2.4 All facilities obtaining blood from human donors for the purpose of transfusion or manufacture of blood products shall report HIV consistent with 6.4.2.2.~~

~~6.4.2.5 Reports of HIV infection required by Section 6.4 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 or treatment. Any other reporting method must be approved in advance and must be in a time frame acceptable to the Division.~~

~~6.4.2.6 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.

~~6.4.2.7 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.~~

7.4.2.5 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.

~~6.4.3 Confidentiality of HIV Reports~~

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. ~~Once this function is completed, the patient's name will be converted to a code and then destroyed. From that time forward, the code will be used in lieu of the name to determine if the patient has been previously reported. In carrying out this function, the Division shall destroy the name as expeditiously as possible, but not later than 90 days from receipt of the report.~~

7.4.3.2 The Division of Public Health will evaluate its procedures for HIV/AIDS named-based reporting on a continuous basis **[~~after implementation~~]** 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.

~~6.4.4 Duty to Disclose the Identity of Sexual or Needle-sharing Partners of HIV Infected Patients~~

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

7.4.4.1 Any ~~physician, or any other licensed health care professional acting on the orders of a physician, (hereafter referred to as provider),~~ 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:

~~a. The patient's condition satisfies the Centers for Disease Control and Prevention definition of AIDS, or has an HIV infection as evidenced by a positive antibody test which is confirmed by Western Blot, or based upon other tests accepted by prevailing medical opinion, the patient is considered to be infected with HIV;~~

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.

~~c. The provider has made reasonable efforts to inform the patient of the intended disclosure and to give the patient the opportunity to express a preference as to whether the partner be notified by the provider, the patient, or the Division.~~

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~~, 6.4.4.1 (d) and 6.4.4.1 (e)~~ 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. ~~Such procedures shall (a) include the requirement that, prior to the Division identifying and notifying a partner, reasonable efforts be made by the Division to counsel the patient and urge the patient's voluntary notification of a partner; (b) specify Division employees permitted to receive the disclosed information; and (c) describe the manner in which partners will be notified pursuant to these regulations.~~

~~6.4.4.4 The provider will prepare and maintain contemporaneous records of compliance with each element of these regulations.~~

7.4.4.4 Division shall have the authority to re-ascertain names for previously reported HIV cases and report them as deemed necessary.

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.

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".

9.0 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").

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.

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.

"[~~Universal~~ 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. **[~~Universal~~ 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 **[~~Universal~~ 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**[~~2~~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 - ~~(1) IgM anti-HAV negative, and (2) IgM anti-Hbc negative or HBsAg negative, and (3) serum aminotransferase level more than two and one half times the upper limit of normal, or anti-HcB positive.~~ 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 meningitides 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 Haem**[o]**philus 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.

11.0 Enforcement

11.1 Authorization

The Department of Health and Social Services or the Director of the Division of Public Health or their designated representatives are authorized to enforce these regulations to accomplish the following:

11.1.1 To insure compliance of persons who refuse to submit themselves or others for whom they are responsible, including their animals, to necessary inspection, examination, treatment, sacrifice of the animal, or quarantine.

11.1.2 To insure coordination of actions of individuals, local authorities, or state authorities in the control of communicable disease.

11.1.3 To insure the reporting of notifiable diseases or other disease conditions as required in these Rules.

11.2 Penalties

Except as otherwise provided by the **Delaware Code** or this regulation, failure to comply with the requirements of this regulation will be subject to prosecution pursuant to 16 **Del.C**., §107. The Department of Health and Social Services may seek to enjoin violations of this regulation.

APPENDIX I
NOTIFIABLE DISEASES

Acquired Immune Deficiency Syndrome (AIDS) (S)
Anthrax (T)
Botulism (T)
Brucellosis
Campylobacteriosis
Chancroid (S)
Chlamydia trachomatis infection (S)
Cholera (T)
CryptosporidiosisPelvic Inflammatory Disease (resulting from gonococcal and/or chlamydial infections) (S)
CyclosporidiosisPertussis (T)
Diphtheria (T)
E. Coli 0157:H7 infection (T)
EncephalitisPsittacosis
EhrlichiosisRabies (man, animal) (T)
Foodborne Disease Outbreaks (T)
GiardiasisRocky Mountain Spotted Fever
Gonococcal Infections (S)
Granuloma Inguinale (S)
Hansen's Disease (Leprosy)
Hantavirus infection (T)
Hemolytic uremic syndrome (HUS)
Hepatitis A (T)
Hepatitis B (S)
Hepatitis C & unspecified (T) (S)
Herpes (congenital) (S)
Herpes (genital) (N)
HistoplasmosisTrichinosis
Human Immunodeficiency Virus (HIV)
Human papillomavirus (genital warts) (N)
Influenza (N)
Lead PoisoningVaccine Adverse Reactions
Legionnaires DiseaseVaricella (N)
LeptospirosisWaterborne Disease Outbreaks (T)
Lyme DiseaseYellow Fever (T)
Malaria
Measles (T)
Meningitis (all types other than meningococcal)
Meningococcal Infections (all types) (T)
Mumps (T)
Nosocomial Disease Outbreak (T)
Pelvic Inflammatory Disease (resulting from gonococcal and/or chlamydial infections) (S)
Pertussis (T)
Plague (T)
Poliomyelitis (T)
Psittacosis
Rabies (man, animal) (T)
Reye Syndrome
Rocky Mountain Spotted Fever
Rubella (T)
Rubella (congenital) (T)
Salmonellosis
Shigellosis
Streptococcal disease (invasive group A)
Streptococcal toxic shock syndrome (STSS)
Syphilis (S)
Syphilis (congenital) (T) (S)
Tetanus
Toxic Shock Syndrome
Trichinosis
Tuberculosis
Tularemia
Typhoid Fever (T)
Vaccine Adverse Reactions
Varicella (N)
Waterborne Disease Outbreaks (T)
Yellow Fever (T)

~~(T) report by rapid means.~~
~~(N) report in number only when so requested~~
~~For all diseases not marked by (T) or (N):~~
~~(S) - sexually transmitted disease, report required in 1 day~~
~~Others - report required in 2 days~~

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

AIDS (S)
Amoebiasis
Anthrax (T)
Arbovir**[~~uses~~al 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
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)
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

~~**APPENDIX II**~~
~~**DRUG-RESISTANT ORGANISMS REQUIRED TO BE REPORTED**~~

~~Staphylococcus aureus intermediate or resistance to Vancomycin (MIC >8ug/ml)~~

~~Streptococcus pneumoniae drug-resistant, invasive disease~~

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