DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)y (16 **Del.C.** §122(3)y)

PROPOSED

4408 Regulations Governing Medical Facilities

PUBLIC NOTICE

House Bill 47 and House Bill 144, signed into law in 2011, give the Department of Health and Social Services (DHSS) the authority to require accreditation for medical facilities that perform invasive medical procedures utilizing any level of anesthesia and allows for the Division to investigate complaints made by patients regarding unsafe or unsanitary conditions. It also gives DHSS the authority to promulgate regulations. The Office of Health Facilities Licensing and Certification, Health Systems Protection Section, Division of Public Health, Department of Health and Social Services, is proposing regulations for medical facilities. On April 1, 2013, DHSS plans to publish as proposed regulations governing medical facilities and hold them out for public comment per Delaware law.

Copies of the proposed regulations are available for review in the April 1, 2013 edition of the Delaware *Register of Regulations*, accessible online at: http://regulations.delaware.gov or by calling the Office of Health Facilities Licensing and Certification at (302) 283-7220.

Any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit same to Deborah Harvey by Tuesday, April 30, 2013 at:

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4408 Regulations Governing Medical Facilities

1.0 General Requirements

1.1 All records maintained by the medical facility shall be open to inspection by the authorized representatives of the Department.

1.2 Reports of adverse events, accidents and medical emergencies shall be kept on file at the facility for a minimum of five years.

1.3 The medical facility must permit photocopying of any records or other information by, or on behalf of authorized representatives of the Department, as necessary to determine or verify compliance with these regulations or accepted standards of practice. The Department shall keep patient information confidential in accordance with state and federal laws.

1.4 Report of adverse events

1.4.1 The facility must report all adverse events involving a patient to the Department within forty-eight (48) business hours of the occurrence.

1.4.2 An adverse event includes but is not limited to:

1.4.2.1 Suspected abuse, neglect, or mistreatment;

1.4.2.2 An accident that causes serious injury to a patient;

1.4.2.3 A procedure on the wrong patient or wrong body part;

1.4.2.4 Serious cardiorespiratory events;

1.4.2.5 Admission to another facility for treatment of complications; or

1.4.2.6 Unexpected death of a patient.

1.4.3 Adverse events must be investigated by the facility.

1.4.4 A complete investigative report will be forwarded to the Department within 30 calendar days of the event.

1.5 A licensed physician/dentist/podiatrist must be available at all times during patient treatment and recovery and until the patients are medically discharged. For those patients that require an extended recovery time, the physician/dentist/podiatrist must be in the facility or on call and immediately available by phone and able to be on-site within 30 minutes.

1.6 All personnel who provide clinical care in a medical facility must be qualified to perform services commensurate with appropriate levels of education, training and experience and in keeping with practice standards. Nothing in these regulations shall prohibit a licensed individual from performing procedures within their scope of practice.

1.7 It is the responsibility of the physician/surgeon/dentist/podiatrist to determine that the medical facility is an appropriate forum for the particular procedure(s) to be performed on the particular patient.

1.8 It is the responsibility of the physician/surgeon/dentist/podiatrist and, when involved, the certified registered nurse anesthetist to determine whether the patient is an appropriate candidate for the anesthesia to be provided in the facility.

1.8.1 The physician/dentist/podiatrist or certified registered nurse anesthetist must examine the patient immediately before the procedure to evaluate the risk of anesthesia and of the procedure to be performed.

1.9 Back-up power, for Level II and III medical facilities, sufficient to ensure patient protection in the event of an emergency shall be immediately available.

1.10 Medical facility procedures shall not:

1.10.1 Generally result in blood loss of more than ten percent of estimated blood volume in a patient with a normal hemoglobin;

1.10.2 Require major or prolonged intracranial, intrathoracic, abdominal or major joint replacement procedures;

1.10.3 Directly involve major blood vessels; or

1.10.4 Be generally emergent or life-threatening in nature.

1.11 There must be sufficient space in the room in which the procedure is being performed. The room shall accommodate all necessary equipment and personnel allowing for expeditious access to the patient and all resuscitation and monitoring equipment.

1.12 All equipment shall be maintained and functional to ensure patient safety.

1.13 All services shall be provided in a safe and effective manner in accordance with accepted standards of practice.

1.14 A Level II or III medical facility that chooses to stop performing invasive medical procedures and voluntarily surrender accreditation, must notify the Department in writing immediately or no later than 30 days following the voluntary surrender of accreditation or cessation of invasive medical procedures.

2.0 Definitions

2.1 The following words and terms, when used in this regulation, should have the following meaning unless the context clearly indicates otherwise:

"**Accredited Medical Facility**" means a medical facility which has received required accreditation from a nationally recognized accrediting organization approved by the Department.

"**Adverse Event**" means the death or serious injury of any patient at a facility; or a reasonable determination by the Department that death or serious injury may result from any unsafe or unsanitary condition at a facility; or the initiation of any criminal investigation arising out of or relating to any diagnosis, treatment or other medical care at a facility.

"**Anxiolysis**" means minimal sedation.

"**ASA Classification**" means the American Society of Anesthesiologists physical classification status of patients used in determining if a medical facility procedure is appropriate.

"**Conscious Sedation**" means moderate sedation.

"**Deep Sedation**" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

"**Dentist**" means an individual currently licensed as such by 24 **Del.C.** Ch. 11.

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

"**General Anesthesia**" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required

because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

"**Invasive Medical Procedure**" means a procedure performed for the purpose of structurally altering the human body by the incision or destruction of tissues (including induced expulsion of a human fetus) and is part of the practice of medicine, dentistry or podiatry. It is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system, is also considered to be an invasive medical procedure (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician/dentist/podiatrist). All of these procedures are invasive, including those that are performed with lasers, and the risks of any procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

"**Local Anesthesia**" means the injection or application of an anesthetic drug to a specific area of the body. Local anesthetics are used to prevent patients from feeling pain during medical, surgical, or dental procedures. Local anesthesia involves the injection into the skin or muscle or application to the skin of an anesthetic directly where pain will occur. Local anesthesia can be divided into four groups: injectable, topical, dental (non-injectable) and ophthalmic. It does include infiltration block anesthesia but would not include procedures in which local anesthesia is injected into areas of the body other than skin or muscle (systemic sedation such as spinal, epidural, axillary, stellate ganglion block, regional blocks (i.e. interscalene), supraclavicular, infraclavicular and intravenous regional anesthesia) where significant cardiovascular or respiratory complications may result.

"**Medical Facility**" means the office of a physician or physician practice, dentist or podiatrist or a clinic where invasive medical procedures utilizing any level of anesthesia are performed. Medical facilities may be classified as Level I, Level II or Level III. Those facilities required to be licensed under Title 16 of the Delaware Code are excluded from this definition.

"**Minimal Sedation**" means a drug-induced state during which patients respond normally to verbal commands. Cognitive and physical coordination may be impaired but airway reflexes and ventilatory and cardiovascular functions are unaffected.

"**Moderate Sedation**" means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

"**Nationally Recognized Accrediting Organization**" means an organization through which a medical facility is able to measure the quality of its services and performance against nationally recognized and evidenced based standards that focus on: ensuring quality health care and provider competence; reducing risks; monitoring standards of practice; promoting continuous quality improvement; and, demonstrating accountability. The organization requires self-assessment by the medical facility, as well as a thorough review by the organization's expert surveyors. Such organizations must be approved by the Department.

"**Nitrous Oxide Inhalation**" means a sedative agent that is mixed with oxygen and inhaled through a small mask that fits over a patient's nose to help the patient relax for a procedure. Nitrous oxide is not intended to put a patient to sleep and the patient should be able to hear and respond to any requests or directions.

"**Patient**" means a person who receives a health care service from a medical facility.

"**Physician**" means an individual currently licensed as such by 24 **Del.C.** Ch. 17.

"Plan of Correction" means a medical facility's written response to findings of regulatory non-compliance. Plans must adhere to the format specified by the Department, must include acceptable timeframes in which deficiencies will be corrected and must be approved by the Department.

"**Podiatrist**" means an individual currently licensed as such by 24 **Del.C.** Ch. 5.

"**Procedure**" means invasive medical procedure.

"**Serious Injury**" means physical injury that creates a substantial risk of death, or that causes serious disfigurement, prolonged impairment of health or prolonged loss or impairment of the function of any bodily organ or which causes the unlawful termination of a pregnancy without the consent of the pregnant female.

"**Time-out**" means a pause in action conducted in the procedure room immediately before the procedure is to begin. The time-out involves the entire operative team, including the patient, uses active communication and includes correctly identifying: the patient, the procedure, and the site.

3.0 Patient Care Levels

3.1 Level I

3.1.1 Procedures are performed under local anesthesia or nitrous oxide inhalation.

3.1.2 Preoperative medications are not required or used other than minimal preoperative oral or intramuscular anti-inflammatory or anti-anxiety producing drugs administered on-site so that the patient can be observed.

3.1.3 Drug-induced alteration of consciousness is not permitted.

3.1.4 Chances of complications requiring hospitalization are remote.

3.1.5 The physician/dentist/podiatrist must have Basic Life Support certification.

3.1.6 The medical facility must maintain basic age and procedure appropriate medications and equipment to manage toxic or hypersensitivity reactions.

3.1.7 The medical facility must maintain and use appropriate sterilization equipment.

3.2 Level II

3.2.1 Procedures performed require the administration of minimal or moderate intravenous, intramuscular or rectal sedation. Intra-procedure and post-procedure monitoring must be completed.

3.2.2 There is a moderate risk of procedural or anesthetic complications and the likelihood of hospitalization as a result of these complications is unlikely.

3.2.3 The physician/dentist/podiatrist will classify each patient using the ASA classification system to determine whether the patient is an appropriate candidate for an invasive medical procedure in the medical facility.

3.2.4 The medical facility must maintain written protocols for the timely and safe transfer of a patient to a hospital for emergency care or hospitalization if necessary.

3.2.5 At least one attending clinical team member must be certified in Advanced Cardiac Life Support.

3.2.6 Equipment and supplies:

3.2.6.1 Crash cart should include:

3.2.6.1.1 Appropriate resuscitative equipment and

3.2.6.1.2 Medications for surgical, procedural or anesthetic complications.

3.2.6.2 Age-appropriate and size-appropriate monitors, resuscitative equipment, supplies and medication in accordance with the scope of the procedures and the anesthesia services provided, including, but not limited to:

3.2.6.2.1 Electrocardiographic monitor;

3.2.6.2.2 Blood pressure monitor;

3.2.6.2.3 Pulse oximeter;

3.2.6.2.4 Continuous suction device;

3.2.6.2.5 Endotracheal tubes;

3.2.6.2.6 Laryngoscopes;

3.2.6.2.7 Positive pressure ventilation device;

3.2.6.2.8 Oxygen;

3.2.6.2.9 Emergency intubation equipment; and

3.2.6.2.10 IV solutions and IV tubing.

3.2.6.3 Appropriate sterilization equipment.

3.2.6.4 Adequate procedure room lighting.

3.2.7 Written informed consent is required prior to the procedure reflecting:

3.2.7.1 The patient's knowledge of the identified risks of the procedure (including anesthesia);

3.2.7.2 The consent to the procedure;

3.2.7.3 The licensed individual performing the procedure;

3.2.7.4 The type of anesthesia to be administered; and

3.2.7.5 The anesthesia provider.

3.2.8 The medical facility must maintain a policy/procedure for a time-out to ensure the risk of medical error is minimized.

3.3 Level III

3.3.1 Procedures performed require the use of deep sedation, general anesthesia or major conduction blockade.

3.3.2 The known complications of the proposed procedure may be serious or life-threatening.

3.3.3 The physician/dentist/podiatrist will classify each patient using the ASA classification system to determine whether patient is an appropriate candidate for an invasive medical procedure in the medical facility.

3.3.4 The medical facility must maintain written protocols for the timely and safe transfer of a patient to a hospital for emergency care or hospitalization if necessary.

3.3.5 At least one attending clinical team member must be certified in Advanced Cardiac Life Support.

3.3.6 A physician/dentist/podiatrist or registered nurse with post-anesthesia care experience and certification in Advanced Cardiac Life Support must monitor the patient in the recovery room until the patient has recovered from the anesthesia.

3.3.7 Equipment and supplies, unless precluded or invalidated by the nature of the patient, procedure, or equipment, including but not limited to:

3.3.7.1 Equipment and supplies required for Level II.

3.3.7.2 Sufficient ampoules of dantrolene sodium or similar FDA approved drug.

3.3.7.3 Esophageal or precordial stethoscope.

3.3.7.4 Temperature monitoring device.

3.3.7.5 End tidal CO_2 monitor.

3.3.8 Written informed consent is required prior to the procedure reflecting:

3.2.8.1 The patient's knowledge of the identified risks of the procedure (including anesthesia);

3.2.8.2 The consent to the procedure;

3.2.8.3 The licensed individual performing the procedure;

3.2.8.4 The type of anesthesia to be administered; and

3.2.8.5 The anesthesia provider.

3.3.9 The medical facility must maintain a policy/procedure for a time-out to ensure the risk of medical error is minimized.

4.0 Infection Control

4.1 The facility must provide and maintain a functional and sanitary environment for procedural services, to avoid sources and transmission of infections and communicable diseases. All areas of the facility must be clean and sanitary.

4.2 Level II and III facilities shall establish and implement an infection prevention and control program which shall be based upon nationally recognized infection control guidelines/standards (i.e. CDC, AORN, etc.).

4.3 The facility must maintain an ongoing program to prevent, control and investigate infections and communicable diseases. As part of this ongoing program, Level II and III facilities must have an active surveillance component that covers both patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.

4.4 Level II and III facilities must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the facility. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the facility's infection control outcomes. The plan should be specific to each particular area of the facility, including, but not limited to, the waiting room(s), the recovery room(s) and the procedure areas.

5.0 Medical Record

5.1 A legible, comprehensive and accurate medical record must be maintained for each patient evaluated or treated.

5.2 The medical record must include:

5.2.1 Patient identifying information

5.2.2 History and Physical:

5.2.2.1 Inclusive of the cardiorespiratory system and other systems related to the diagnosis;

5.2.2.2 Completed within 30 days prior to the procedure for any patient who will receive more than a local anesthesia or nitrous oxide inhalation

5.2.3 Diagnosis and plan

5.2.4 Appropriate diagnostic reports

5.2.5 Informed consent for Levels II & III

5.2.6 Documentation of the time-out for Levels II & III

5.2.7 Adequate written documentation of the procedure

5.2.8 Pathology reports

5.2.9 Outcome and follow-up plans

5.2.10 Documentation of anesthesia used:

5.2.10.1 A separate anesthesia record must be kept for all anesthesia/sedation, other than local.

5.2.10.2 Documentation must include:

5.2.10.2.1 Type of anesthesia

5.2.10.2.2 Drug type, dose and route

5.2.10.2.3 Time of administration

5.2.10.2.4 Fluids administered

5.2.10.2.5 Patient weight

5.2.10.2.6 Vital signs monitoring

5.2.10.2.7 Estimated blood loss

5.2.10.2.8 Duration of procedure

5.2.10.2.9 Any complication or unusual event related to the procedure or anesthesia.

5.2.11 Intra-procedure and post-procedure monitoring.

5.3 The medical facility must ensure the security and confidentiality of the medical record in accordance with state and federal laws.

6.0 Patient Rights

6.1 The medical facility must post written notice of patient rights in a place or places within the facility likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The facility's notice of rights must include the names, addresses, and telephone numbers of the State agencies and accrediting organization to whom patients can report complaints.

6.1.1 Complaints received by the Department will be investigated as appropriate.

6.1.2 Complainants (unless anonymous) will be notified of the outcome of any investigation.

6.2 The patient has the right to:

6.2.1 High quality care delivered in a safe, timely, efficient and cost-effective manner and the right to be assured that the expected results can be reasonably anticipated.

6.2.2 Dignity, respect and consideration of legitimate concerns.

6.2.3 Privacy and confidentiality.

6.2.4 Be involved in all aspects of care:

6.2.4.1 Informed consent must be obtained after discussion of the risks, benefits and alternatives for the procedure.

6.2.4.2 The patient must be given information about the current diagnosis, treatment and prognosis.

6.2.5 Refuse any procedure or treatment and to be advised of the likely medical consequences of such refusal.

6.2.6 Know who will be delivering the care and the qualifications of such individuals.

6.2.7 Exercise her/his rights without being subjected to discrimination or reprisal.

6.2.8 Voice grievances regarding treatment or care that is (or fails to be) furnished.

6.2.9 Be free from all forms of abuse, mistreatment or harassment.

6.2.10 Be served by individuals who are properly trained and competent to perform their duties.

7.0 Disciplinary Actions

7.1 The Department may impose sanctions singly or in combination when it finds a medical facility has:

7.1.1 Violated any of these regulations;

7.1.2 Violated standards for safe and sanitary care in a medical facility;

7.1.3 Failed to correct deficiencies in accordance with a timetable submitted by the facility and agreed upon by the Department;

7.1.4 Engaged in any conduct or practices detrimental to the welfare of the patients; or

7.1.5 Refused to allow the Department access to the agency or records for the purpose of conducting inspections/surveys/investigations as deemed necessary by the Department.

7.2 Disciplinary sanctions:

7.2.1 The Department may make and enforce such orders as it deems necessary to protect the health and safety of the public.

7.2.1.1 If the Department determines during the course of any investigation or inspection that any medical facility poses a substantial risk to the health or safety of any person, the Department may order that such facility be closed until such time as it no longer poses a substantial risk.

7.2.1.1.1 An order of closure under this section shall remain in effect for a period not longer than 60 calendar days from the date of the issuance of said order, unless the facility requests a continuance of the date for the final hearing before the Department.

7.2.1.2 If the Department determines during the course of any investigation or inspection that any medical facility poses a possible risk to the health or safety of any person, the Department may:

7.2.1.2.1 Issue of a letter of reprimand and/or

7.2.1.2.2 Require the medical facility to complete a plan of correction.

7.3 Imposition of Disciplinary Action

7.3.1 The Department may issue an order to close the facility immediately.

7.3.1.1 An order to close may apply to the performance of invasive medical procedures.

7.3.1.2 An order to close may apply to the facility as a whole.

7.3.2 The medical facility shall be notified forthwith in writing. The order to close shall be personally served upon the medical facility or sent by mail, return receipt requested, to the medical facility's last address of record.

7.3.2.1 A statement of deficiencies (identified during the investigation/inspection) will be forwarded to the medical facility within 48 hours of completion of the investigation/inspection.

7.3.3 In response to the order to close, the medical facility may:

7.3.3.1 Take no action, in which case the order to close shall remain in effect.

7.3.3.2 Take action to correct the unsafe and unsanitary practices identified during the survey.

7.3.3.2.1 The facility may submit evidence through a written plan of correction showing that the deficient practices, identified during the investigation, have been addressed and corrected.

7.3.3.2.1.1 A change of location for the facility does not nullify an order to close and an acceptable plan of correction must still be submitted.

7.3.3.2.2 The Department shall determine if the plan of correction is acceptable.

7.3.3.2.3 Once accepted, the Department shall schedule a revisit as soon as possible.

7.3.3.3 Request, in writing, an administrative hearing with the Secretary of the Department to contest the order to close.

7.3.3.3.1 Such request must be received within 20 calendar days from the date on which the order to close was issued.

7.3.3.3.1.1 As soon as possible, but in no event later than 60 calendar days after the issuance of the closure order, the Department shall convene a hearing on the reasons for closure.

7.3.3.3.1.2 The Department shall make a determination based upon the evidence presented.

7.3.3.3.1.3 A written copy of the determination and the reasons upon which it is based shall be sent to the facility within 30 calendar days.

7.3.3.3.2 A facility may request an expedited hearing.

7.3.3.3.2.1 The Department shall schedule the hearing on an expedited basis provided that the Department receives the facility's written request for an expedited hearing within five (5) calendar days from the date on which the facility received notification of the Department's decision to close the facility.

7.3.3.3.2.2 The Department shall convene an expedited hearing within 15 calendar days of the receipt by the Department of such a request.

7.3.3.3.2.3 The Department shall make a determination based upon the evidence presented.

7.3.3.3.2.4 A written copy of the determination and the reasons upon which it is based shall be sent to the facility within 30 calendar days.

7.3.4 During an administrative hearing:

7.3.4.1 The facility has the right to be represented by counsel.

7.3.4.2 All statements made shall be under oath.

7.3.4.3 The facility has the right to cross-examine witnesses.

7.3.4.4 A stenographic recording will be made.

7.3.5 As a result of the hearing, the order to close may be continued, modified or revoked.

7.3.6 A facility may appeal the decision of the Department to the Superior Court.

8.0 Accreditation Requirements and Procedures

8.1 General requirements

8.1.1 All medical facilities must register with the Department using a form created by the Department. It will include physician/office name, address, phone number, acknowledgment that invasive procedures are performed and level(s) of anesthesia used in the facility.

8.1.2 No person shall establish, conduct or maintain in this State any Level II or III medical facility without obtaining accreditation from a nationally recognized accrediting organization that is approved by the Department.

8.1.3 Level II or III medical facilities must provide proof of accreditation to the Department within 12 months of the first day of operation of such facility.

8.1.4 The accreditation certificate shall be posted in a conspicuous place on the Level II or III medical facility premises, at or near the entrance in a manner which is plainly visible and easily read by the public.

8.1.5 Level II or III medical facilities must submit an accreditation certificate to the Department within 30 days of each accrediting organization survey.

8.1.5.1 The Department shall accept the accreditation certificate of an approved accrediting organization in lieu of a licensure inspection.

8.1.5.2 The Department may request and the medical facility must submit a copy of the entire accreditation report.

8.1.5.3 Level II or III medical facilities required to submit a plan of correction to an accrediting organization may also be required to submit a copy of the plan of correction to the Department.

8.2 Accreditation termination

8.2.1 Termination of accreditation may occur secondary to:

8.2.1.1 Voluntary surrender of accreditation by the medical facility.

8.2.1.2 Revocation of accreditation by the accrediting organization.

8.2.1.3 Any other valid reason.

8.2.2 Any Level II or III medical facility that fails to maintain accreditation shall immediately cease to perform invasive medical procedures.

8.3 Inspection

8.3.1 Unannounced inspections of any medical facility by authorized representatives of the Department may occur:

8.3.1.1 Anytime upon receipt of a complaint by a patient, spouse, parent, legal guardian or legal custodian or upon the occurrence of any adverse event.

8.3.1.2 Anytime upon receipt of a referral from the Division of Professional Regulations.

8.4 Notice to patients

8.4.1 The Level II or III medical facility shall notify each patient (or the patient's authorized representative) scheduled for an upcoming invasive medical procedure of an accreditation termination or as directed under an order issued by the Department and shall include information regarding alternative healthcare providers.

8.5 Exclusions from accreditation

8.5.1 The following persons, associations or organizations are not required to obtain accreditation as medical facilities:

8.5.1.1 Those facilities required to be licensed under Title16 of the Delaware Code.

8.5.1.2 Level I medical facilities.

9.0 Severability

In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.