Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

# DEPARTMENT OF HEALTH AND SOCIAL SERVICES

## DIVISION OF PUBLIC HEALTH

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

## FINAL

### ORDER

### 4408 Facilities that Perform Invasive Medical Procedures

### NATURE OF THE PROCEEDINGS:

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Facilities that Perform Invasive Medical Procedures. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Del.C.** § 122(3)y and z.

On October 1, 2013 (Volume 17, Issue 4), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by October 31, 2013, after which time the 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."

### SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Facilities that Perform Invasive Medical Procedures were published in the *Delaware State News*, the *News Journal* and the Delaware *Register of Regulations*.

Entities offering written comments include:

- Medical Society of Delaware, Stephen J. Kushner, D.O., President
- State Council for Persons with Disabilities, Denise McMullin-Powell, Chairperson
- Governor's Advisory Council for Exceptional Citizens, Terri A. Hancharick, Chairperson
- Anesthesia Advisory Consultants, Lawrence S. Giordano, DDS (Recent Former Consultant); and, Raymond Petrunich, DMD (Current Consultant)

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

**Medical Society of Delaware, Stephen J. Kushner, D.O., President:**

On behalf of the Medical Society of Delaware, thank you for your diligent work in the crafting of these proposed regulations and for the opportunity to provide comments. In this letter we offer a number of technical amendments and suggestions. We also would like to restate an overarching concern we submitted in April, 2013. However, we appreciate your efforts and care in the process.

While we recognize the statutory requirements as to the scope of these regulations, we would like to briefly reiterate our letter sent in response to the April version of these regulations. That is, the Medical Society is concerned that these regulations improperly intermingle facility specifications and practitioner conduct. The statutory and regulatory combination of these separate concerns confuses the facility standards with the practice of medicine in reporting "adverse events." Incidents in the practice of medicine should be left to the purview of the Board of Medical Licensure and Discipline and such changes should be included in their regulations.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency disagrees that the reporting of adverse events will improperly intermingle facility specifications and practitioner conduct. The reporting of adverse events will facilitate the monitoring of the safe and sanitary environment within facilities that perform invasive medical procedures. The regulations do not regulate physician licenses or practice; only the safety of the care provided in the facilities that perform invasive medical procedures. Issues related to physician licensure will continue under the oversight of the Division of Professional Regulation.

Additionally, we suggest the following technical amendments:

- 2.0 Definitions – The definition "Anxiolysis" references the definition of "Minimal Sedation" which "means a drug-induced state during which: (1) patients respond normally to verbal commands, (2) cognitive and physical coordination may be impaired but airway reflexes and ventilatory and cardiovascular functions are unaffected." Clinically, anxiolysis is broad and anything that relieves anxiety falls under the definition. Thus use of common anxiety medications such as any of the range of oral benzodiazepines would trigger "minimal sedation" and "Anesthesia" which is likely not the intent. We would suggest a curbed definition of Anxiolysis which would read: "means minimal sedation, as defined below, delivered intravenously" or by similar narrowing language.

***Agency Response:*** The Agency appreciates and acknowledges these comments. Upon consideration of the comment and review of current literature, the Agency will further clarify the definition of anesthesia to exclude (1) the administration of less than 50% nitrous oxide in oxygen with no other sedative or analgesic medications by any route or (2) a single, oral sedative or analgesic medication administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.

- 3.8 could be worded more clearly. Does the qualification of requiring "post-anesthesia care experience and certification in [ACLS]" apply to all in that list or only to a registered nurse? We believe the intent is the latter, but it is ambiguous.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The language referencing the post-anesthesia care experience and certification in advanced cardiac life support requirement in 3.8 is specific to the registered nurse. The regulation wording will be re-ordered to clearly reflect this requirement.

- 3.9 under Patient Care is overreaching. Requiring a physician/dentist/podiatrist to be on-site at all times until medical discharge does not take into account the role of other medical staff in facilities and the relationship facilities have with emergency providers. We suggest either expanding the list, requiring a formal relationship with emergency services, or striking this provision.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The standards of practice require the practitioner that performed that invasive medical procedure be onsite and immediately available until the patient is discharged from the facility; therefore, the regulation will remain as written.

- 4.3.3 states that "[t]he facility must forward a complete investigative report to the Department within 30 calendar days of the event." Will a template or parameters be provided by the Department?

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will not have a template to complete investigative reports. However, in the event of an adverse event, the facility will be expected to complete a root cause analysis of the incident and provide the Department with a thorough investigative report including details of the incident, the root cause analysis, follow-up that was completed as a result of the incident/investigation and any other pertinent information.

- 4.7.1 states "[t]he facility shall develop and maintain policies and procedures based upon accepted standards of practice." This is a broad requirement. Facilities follow standards of practice developed by professional and regional organizations and are not in the position to develop them. Striking "develop and" may be sufficient.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency agrees and will revise the regulation to state, "The facility shall maintain policies and procedures based upon accepted standards of practice."

- 4.11 requires that a facility that chooses to stop performing invasive medical procedures and voluntarily surrenders accreditation must notify the Department in writing 30 days prior to the voluntary surrender of accreditation or cessation of invasive medical procedures. Why is this time requirement necessary? While closures do happen, a checklist to ensure a facility closes without harming patients may help avoid unnecessary financial hardships that are inadvertently possible in a 30 day requirement.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency disagrees and the regulation will remain as written. The intent of this regulation is to ensure patients receive safe care in the event that a facility chooses to voluntarily surrender accreditation and stop performing invasive medical procedures.

As to Section 8.0 Disciplinary Actions, the Medical Society has concerns both at the broad discretion granted the Department as well as the time frames during which a facility may be closed. In the rare occasion that facilities have to close to address concerns, the goal should be to re-open these facilities as quickly as possible, not only to ensure their viability as small businesses, but to make sure Delawareans continue to receive necessary care.

- Under 8.2.1.1, the standard of "immediate and substantial risk to the health or safety of any person" is undefined and overbroad. While we appreciate the need for the Department to have flexibility to address health concerns, baseline criteria would help guide all stakeholders and set a standard for any administrative hearings.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The goal of the Department is to ensure the safety of those Delawareans receiving services in facilities that perform invasive medical procedures. Because of the broad range of invasive medical procedures that are performed in these facilities, this regulation, as written, provides the appropriate latitude to determine compliance with a multitude of standards. The Department agrees with the Medical Society and the goal will be to re-open these facilities as quickly as possible, not only to ensure their viability as small businesses, but to make sure Delawareans continue to receive necessary care.

- Under 8.2.1.1.1, we appreciate a cap of 90 days for a closure and a mechanism for continuance if requested, but the time frames within the 90 days are far too long. An expedited hearing under 8.3.3.3.2 is a useful mechanism, but 15 days for action upon receipt and then another 30 days—the starting point of which is unclear, we suggest starting the time at the time of the order—for a decision are both also too long. We would like to point out that food establishments closed for imminent health hazards receive faster regulatory hearings. Under Delaware Food Code 8-602.10(B)(2), a permit holder "shall not be suspended for a period longer than ten (10) government business days without a hearing. Failure to hold a hearing within the ten (10) government business day period shall automatically terminate the suspension." The Medical Society suggests that keeping

medical facilities open and serving the public is as important as keeping our food establishments open and would request similar or faster time frames as well as an extinguishing cap that would allow facilities to re-open if no timely action is taken.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The timeframes included within these regulations are in compliance within the Administrative Procedures Act within Delaware Code.

- Related, we appreciate and value the mechanism that allows a plan to be submitted to correct unsafe practices, but we suggest both 8.3.3.2.2 and 8.3.3.2.3 have a faster required response rate. Perhaps a new 8.3.3.2.4 which states "The Department shall evaluate a plan and revisit a closed facility within 48 hours or 72 hours if including non-government business days" to ensure that facilities are able to resume treating those in need as soon as possible.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Department will review the plan of correction immediately upon receipt and a revisit will be conducted expeditiously upon the receipt of an acceptable plan of correction.

- Lastly, 8.3.1.2 allows for closing an entire facility and not just the performance of medical procedures. While situations may arise, although hopefully not, where this is required, there should be a mechanism to allow a facility to be able to quickly and reliably resume practice if the problem is contained.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The mechanism for a facility to resume practice already exists through the submission and implementation of an acceptable plan of correction as outlined in the regulations.

**State Council for Persons with Disabilities, Denise McMullin-Powell, Chairperson:**

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/ Division of Public Health's (DPH's) proposal to adopt a new regulation regarding facilities that perform invasive procedures using anesthesia. The proposed regulation was published as 17 **DE Reg.** 397 in the October 1, 2013 issue of the Register of Regulations. SCPD provided commentary on the initial set of proposed regulations in April 2013 and has the following observations on the revised version.

**Governor's Advisory Council for Exceptional Citizens, Terri A. Hancharick, Chairperson:**

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Division of public Health (DPH) proposal to adopt new regulations regarding facilities that perform invasive procedures using anesthesia. The GACEC provided commentary on the initial set of proposed regulations in April 2013 and would like to share the following observations on the revised version.

**The State Council for Persons with Disabilities and The Governor's Advisory Council for Exceptional Citizens submitted the following comments:**

1. In §2.0, definition of "accredited facility", second sentence, SCPD, GACEC recommends insertion of "the" between "from" and "facility".

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will insert the word "the" between "from" and "facility".

2. In §2.0, definition of "accredited organization", second sentence, SCPD, GACEC recommends the following revision - "...organization requires facilities to complete self-assessments and expert surveyors to conduct thorough reviews."

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency acknowledges the lack of a preposition and will change the definition of "accrediting organization" to "...organization requires facilities to complete self-assessments and expert surveyors to conduct thorough reviews."

3. In §2.0, the definition of "certified registered nurse anesthetist" is simply "an individual currently licensed under 24 **Del.C.** Ch. 19." This definition is problematic since it would literally mean anyone licensed under that chapter (LPN; RN; APN) qualifies as a nurse anesthetist under the regulations. There is no separate license or certification of a nurse anesthetist mentioned in Chapter 19, only a passing reference in §1902(b)(1).

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will clarify the definition of "certified registered nurse anesthetist" to read, "an individual currently licensed as an advanced practice nurse currently licensed under 24 **Del.C.** Ch. 19."

4. In §2.0, definition of "general anesthesia", SCPD, GACEC recommends not capitalizing "(t)he in Par. (2) and inserting "and" before "(4)".

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will not capitalize "(t)he" in Par. (2) and insert "and" before "(4)".

5. In §2.0, definition of "invasive medical procedure', the reference to "major conduction anesthesia or sedation" is surplusage since the terms are included in the definition of "anesthesia.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The definition of "invasive medical procedure" reflects the statutory definition and will remain as written.

6. In §2.0, definition of "minimal sedation, SCPD, GACEC recommends inserting "and" before "(2)".

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will insert the word "and" before "(2)".

7. In §2.0, the definitions of “physician” and “physician assistant” are identical. Consider the following revisions:

“**Physician**” means an individual currently licensed as a physician under 24 **Del.C.** Ch. 17.

**“Physician Assistant”** means an individual currently licensed as a physician assistant under 24 **Del.C.** Ch. 17.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will clarify the definitions of “physician” and “physician assistant” to read “**Physician** means an individual currently licensed as a physician under 24 **Del.C.** Ch. 17” and **“Physician Assistant** means an individual currently licensed as a physician assistant under 24 **Del.C.** Ch. 17”.

8. In §2.0, definition of “time-out”, the reference to “site” is not intuitive. It suggests that the team does not know its location.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The standard requirements of a “time-out” include correctly identifying the patient, the procedure and the site; therefore, the definition of “time-out” will remain as written.

9. In §3.2, insert a comma after “anesthetist”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will insert a comma after “anesthetist”.

10. In §3.5.1.11, delete “and”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will delete “and” at the end of §3.5.1.11.

11. In §3.5.1.12, substitute a semicolon for the period.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will substitute a semicolon for the period after the word “monitor” in §3.5.1.12.

12. In §3.5.1.13, insert “which” between “cart” and “include”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will insert the word “which” between “cart” and “include” in §3.5.1.13.

13. In §3.5.1.13.2, substitute a semicolon for the period. Compare §6.2.2.2.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will substitute a semicolon for the period in §3.5.1.13.2.

14. In §3.5.2, substitute “; and” for the period.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will substitute “; and” for the period at the end of §3.5.2.

15. In §4.6, substitute “prohibit licensed individuals” for “prohibit a licensed individual” since there is otherwise a plural pronoun (“their”) which refers back to a singular noun (“individual”).

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will replace the word “their” with “his/her” to resolve conflict between a plural pronoun and a singular noun.

16. In §4.11, delete the comma after “accreditation”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will delete the comma after the word “accreditation” in §4.11.

17. In §5.1, delete the comma after “environment”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will delete the comma after the word “environment” in §5.1.

18. In §6.2.7, add a semicolon.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will add a semicolon at the end of §6.2.7.

19. In §6.2.8, delete “and”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will delete the word “and” at the end of §6.2.8.

20. In §6.2.9, insert a semicolon.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will insert a semicolon at the end of §6.2.9.

21. Delete §§6.2.10.1 and 6.2.10.2 while amending §6.2.10 to read as follows: “A separate anesthesia record for each administration of anesthesia which must include:”

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency recognizes the similarity of the requirements and will amend §6.2.10 to read “A separate anesthesia record for each administration of anesthesia which must include:” Therefore, §§6.2.10.1 and 6.2.10.2 will be deleted as the requirements will be contained in §6.2.10.

22. Renumber §§6.2.10.2.1 through 6.2.10.2.9 as 6.2.10.1 through 6.2.10.9. Substitute “; and” for the period after the renumbered 6.2.10.9.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will renumber §§6.2.10.2.1 through 6.2.10.2.9 as 6.2.10.1 through 6.2.10.9; however, the period after the renumbered 6.2.10.9 will

remain.

23. Delete the comma after “near”.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Agency will delete the comma after “near” in §7.1.

24. Section 8.2.1.1.1 categorically caps the duration of an order of closure to 90 days in the absence of a request for continuance of the date of a Departmental hearing. This is problematic.

A. Under §§8.3.3.3.1 and 8.3.3.3.1.1, a hearing could routinely occur on the 80th day after issuance of the closure order and §8.3.3.3.1.3 suggests that the hearing decision could be issued on the 110th day. During days 91-109, the closure order would no longer be in effect and the facility could reopen. If a continuance were granted per 8.2.1.1.1, this time period would be extended and the facility could reopen for an even longer period.

B. Under §8.3.3.1, if the facility takes no action on an order of closure, the order of closure remains in effect. It is not capped at 90 days per §8.2.1.1.1.

***Agency Response:*** The Agency appreciates and acknowledges these comments. If a facility requests a hearing, the request must be received by the Department within 20 calendar days from the date on which the order to close was issued and the hearing must be held within 60 days from the date on which the order to close was issued; therefore, completing the entire process within the 90 day timeframe. The 90 day timeframe is to ensure the timely resolution for those facilities requesting an administrative hearing and those facilities choosing to address and correct the issues leading to an order to close. If a facility takes no action to correct the issues that led to the order to close, the facility must remain closed. The regulation will remain as written.

25. Section 9.3.1 addresses unannounced inspections. SCPD, GACEC recognizes that §9.3.1.1 mirrors the statute. However, the Department’s licensing authority might also authorize unannounced inspections at any time. As written, §9.3 would arguably bar the Department from initiating an unannounced inspection in the absence of a complaint or DPR referral. The Division may wish to add a catch-all provision (§9.3.1.3) to read as follows: “Anytime as otherwise authorized by law or applicable regulation.”

***Agency Response:*** The Agency appreciates and acknowledges these comments. The regulation will remain as written.

26. The exclusion in §9.5.1.1 is contrary to the statutory definition of “facility”. See Title 16 **Del.C.** §122(3)y.3.C. If the Stockley Center, Mary Campbell Center, or other long-term care facility engaged in invasive procedures (including dental and podiatry procedures), they should be required to comply with the regulation.

***Agency Response:*** The Agency appreciates and acknowledges these comments. The Stockley Center, Mary Campbell Center and other long-term care facilities, and the healthcare services provided within these facilities, are regulated by Title 16 Chapter 11.

**Anesthesia Advisory Consultants, Lawrence S. Giordano, DDS (Recent Former Consultant); and, Raymond Petrunich, DMD (Current Consultant):**

We have been Anesthesia Advisory Consultants to the Board of Dentistry for many years. We have been administering the regulations concerning dentists (under Title 24, 1100 Board of Dentistry, 7.0 to 7.6.3. for at least 25 years.

As we read the proposed regulations of “4408 Facilities that Perform Invasive Medical Procedures”, we note the definitions of the various types of anesthesia and sedations, which includes the definition of Anxiolysis or (more recently called) Minimal sedation. While this is a quite logical inclusion when defining types of sedation, it creates an unnecessary problem for dentists. That problem is that this inclusion would now require all dentists who utilize minimal sedation to be inspected.

As you may also know, the regulations concerning anesthesia for dentists can issue three different types of Permits. Each dentist must qualify for the specific Permit he/she is applying for, and then must fulfill that Permits requirements. The Permit for Minimal sedation (only) is called a Restricted II Permit, and requires the dentist to have taken a specific course of at least 14 hours, and it must include actual patient administration, under personal supervision by an instructor. This is better understood as nitrous oxide inhalation sedation, unfortunately sometimes called “laughing gas”.

Most dentists will meet this requirement in Dental School, and if they submit official documentation of the course, we (the AAC, Anesthesia Advisory Consultants) recommend to the Board that they be granted a Restricted II Permit. Inspection of their facility is not required by our regulations because we believe this technique is particularly safe, the equipment is not complicated, they have been adequately trained to administer this technique, and the equipment has “fail safety” built into it.

For example, the machines limits how high a concentration one could use, and if somehow oxygen is lost, then no nitrous oxide will flow, etc.

So that you fully appreciate the Anesthesia regulations, the other two Permits do require an initial inspection, and a re-inspection every five years. These inspections are delineated in the regulations and are very comprehensive, especially as it relates to the Unrestricted Permit.

The AAC must use the criteria developed by the American Association of Oral and Maxillofacial Surgeons when it does the inspections. These criteria have been developed in liaison with the American Society of Anesthesiologists, American Dental Association (and many other pertinent organizations).

While we have no documentation to prove it, we think there is no other medical specialty who would use “Minimal sedation”, as we use it in dentistry (which in practicality, means the use of Nirous Oxide Inhalation as the sedative agent and technique). Thus, dentists would be the only ones affected by this inclusion, and the AAC does not think this is necessary.

Obviously, none of these comments relate to other requirements of the law, but only as it relates to anesthesia and sedation by dentists.

We therefore ask that an exemption be given to dentists who have a Restricted II Permit, from the requirement of inspection of their facility, as it relates to anesthesia/sedation.

***Agency Response:*** The Agency appreciates and acknowledges these comments. Upon consideration of the comment and review of current literature, the Agency will further clarify the definition of anesthesia to exclude (1) the administration of less than 50% nitrous oxide in oxygen with no other sedative or analgesic medications by any route or (2) a single, oral sedative or analgesic medication administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.

The public comment period was open from October 1, 2013 through October 31, 2013.

Based on comments received during the public comment period, only non-substantive changes have been made to the proposed regulations. The regulations have been approved by the Delaware Attorney General’s office and the Cabinet Secretary of DHSS.

**FINDINGS OF FACT:**

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

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Facilities that Perform Invasive Medical Procedures are adopted and shall become effective February 11, 2014, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

## 4408 Facilities that Perform Invasive Medical Procedures

### 1.0 Purpose

Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 **Del.C.** §122(3)(y and z). These regulations establish standards with respect to the safe and sanitary conditions, and require the accreditation of any facility that performs invasive medical procedures in which the accepted standard of care requires anesthesia, major conduction anesthesia, or sedation. These regulations also provide for the investigation of any patient or current facility employee complaints involving the unsafe and/or unsanitary conditions in such facilities.

### 2.0 Definitions

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

**"Accredited Facility"** means a facility that is accredited by an accrediting organization approved by the Department. Approval requires an accrediting organization to be independent from **[the]** facility.

**"Accrediting Organization"** means an organization able to measure the quality of facility's services and performance against nationally-recognized and evidenced-based standards that focus on (1) ensuring quality health care and provider competence, (2) reducing risks, (3) monitoring standards of practice (4) promoting continuous quality improvement, and (5) demonstrating accountability. The organization requires facilities **[to]** complete self-assessments and expert surveyors **[to]** conduct thorough reviews.

**"Adverse Event"** means the death or serious injury of any patient at a facility; 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.

**"Anesthesia"** means anxiolysis, conscious sedation, deep sedation, major conduction anesthesia, minimal sedation, moderate sedation or general anesthesia. **[~~Local anesthesia is not included in this definition~~ This definition excludes: (1) local anesthesia, (2) the administration of less than 50% nitrous oxide in oxygen with no other sedative or analgesic medications by any route, or (3) a single, oral sedative or**

**analgesic medication administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain]**.

**"Anxiolysis"** means minimal sedation.

**"ASA Classification"** means the American Society of Anesthesiologists's physical status classification of preoperative patients for anesthetic risk assessment.

**"Certified Registered Nurse Anesthetist"** means an individual currently licensed **[as an advanced practice nurse]** under 24 **Del.C.** Ch.19.

**"Complaint"** means a complaint filed by a patient or current facility employee in writing, in such format as the Department requires.

**"Conscious Sedation"** means moderate sedation

**"Deep Sedation"** means a drug-induced depression of consciousness during which: (1) patients cannot be easily aroused but respond purposefully following repeated or painful stimulation, (2) the ability to independently maintain ventilatory function may be impaired, (3) patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate, and (4) cardiovascular function is usually maintained.

**"Dentist"** means an individual currently licensed **[as a dentist]** under 24 **Del.C.** Ch. 11.

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

**"Facility"** means a location at which any invasive medical procedure is performed, but shall not include any hospital, as defined in 16 **Del.C.** §1001(2), or any freestanding birthing center, freestanding surgical center or freestanding emergency center as such terms are defined in defined in 16 **Del.C.** §122 (3)p.

**"General Anesthesia"** means a drug-induced loss of consciousness during which: (1) patients are not arousable, even by painful stimulation, (2) **[~~T~~t]**he ability to independently maintain ventilatory function is often impaired, (3) 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, **[and]** (4) cardiovascular function may be impaired.

**"Invasive Medical Procedure"** means any medical procedure, including dental and podiatric procedures, in which the accepted standard of care requires anesthesia, major conduction anesthesia or sedation.

**"Local Anesthesia"** means the injection of the skin or muscle, or application of an anesthetic drug to a specific area of the body, to prevent patients from feeling pain directly where the pain will occur during a medical, surgical or dental procedure. Local anesthesia can be divided into four groups: injectable, topical, dental (non-injectable) and ophthalmic. Local anesthesia 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 (i.e. systemic sedation such as spinal, epidural, axillary, stellate ganglion block, regional blocks, supraclavicular, intraclavicular and intravenous regional anesthesia) where significant cardiovascular or respiratory complications may result.

**"Major Conduction Anesthesia"** means the administration of a drug, or a combination of drugs, to interrupt nerve impulses without loss of consciousness, e.g. epidural, caudal, or spinal anesthesia, lumbar or brachial plexus blocks, and intravenous regional anesthesia. However, isolated blockade of small peripheral nerves, such as digital nerves are not included.

**"Minimal Sedation"** means a drug-induced state during which: (1) patients respond normally to verbal commands, **[and]** (2) 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: (1) patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation, (2) no interventions are required to maintain a patent airway, (3) spontaneous ventilation is adequate, and (4) cardiovascular function is usually maintained.

**"Patient"** means a person, person's spouse, parent, legal guardian, or legal custodian of a person under 18 or any legal guardian or legal custodian of a person who is an adult, who has received diagnosis, treatment or other medical care at a facility.

**"Physician"** means an individual currently licensed **[as a physician]** under 24 **Del.C.** Ch. 17.

**"Physician Assistant"** means an individual currently licensed **[as a physician assistant]** under 24 **Del.C.** Ch. 17.

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

**"Podiatrist"** means an individual currently licensed **[as a podiatrist]** under 24 **Del.C.** Ch. 5.

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

**"Registered Nurse"** means an individual currently licensed **[as a registered nurse]** under 24 **Del.C.** Ch.19.

**"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 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 (1) involves the entire operative team, including the patient, (2) uses active communication and (3) includes correctly identifying: the patient, the procedure, and the site.

**3.0 Patient Care**

3.1 The physician/dentist/podiatrist must determine that the facility is an appropriate forum for the particular procedure(s) to be performed on the particular patient.

3.2 The physician/dentist/podiatrist and/or when involved, the certified registered nurse anesthetist**[,]** must determine whether the patient is an appropriate candidate for the anesthesia to be provided in the facility using the ASA classification system.

3.2.1 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.

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

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

3.5 The facility must maintain equipment and supplies, unless precluded or invalidated by the nature of the patient, procedure, or equipment, including but not limited to:

3.5.1 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:

3.5.1.1 Electrocardiographic monitor;

3.5.1.2 Blood pressure monitor;

3.5.1.3 Pulse oximeter;

3.5.1.4 Continuous suction device;

3.5.1.5 Positive pressure ventilation device;

3.5.1.6 Oxygen;

3.5.1.7 Emergency intubation equipment;

3.5.1.8 IV solutions and IV tubing;

3.5.1.9 Sufficient ampoules of dantrolene sodium or similar FDA approved drug, if the facility utilizes anesthetic agents that trigger malignant hyperthermia;

3.5.1.10 Esophageal or precordial stethoscope;

3.5.1.11 Temperature monitoring device;**[and]**

3.5.1.12 End tidal CO2 monitor**[.;]**

3.5.1.13 Crash cart **[which]** shall include:

3.5.1.13.1 Appropriate resuscitative equipment; and

3.5.1.13.2 Medications for surgical, procedural or anesthetic complications**[.;]**

3.5.2 Appropriate sterilization equipment**[.; and]**

3.5.3 Adequate procedure room lighting.

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

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

3.6.2 The consent to the procedure;

3.6.3 The licensed individual performing the procedure;

3.6.4 The type of anesthesia to be administered; and

3.6.5 The anesthesia provider.

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

3.8 A **[registered nurse with post-anesthesia care experience and certification in Advanced Cardiac Life Support or a]** physician/dentist/podiatrist/physician assistant/certified registered nurse anesthetist **[~~or~~**

**~~registered nurse with post-anesthesia care experience and certification in Advanced Cardiac Life Support~~]** must monitor the patient until the patient has met the facility's criteria for discharge.

3.9 A physician/dentist/podiatrist must be available onsite during patient treatment and until the patients are medically discharged.

## 4.0 General Requirements

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

4.2 The 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.

4.3 Report of adverse events:

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

4.3.2 The facility must conduct an investigation of all adverse events.

4.3.3 The facility must forward a complete investigative report to the Department within 30 calendar days of the event.

4.4 The facility must keep reports of adverse events, accidents and medical emergencies on file at the facility for a minimum of five years.

4.5 Facility procedures shall not:

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

4.5.2 Include major or prolonged intracranial, intrathoracic, abdominal or major joint replacement procedures;

4.5.3 Directly involve major blood vessels; or

4.5.4 Be generally emergent or life-threatening in nature.

4.6 All personnel who provide clinical care in a 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~~ his/her]** scope of practice.

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

4.7.1 The facility shall **[~~develop and~~]** maintain policies and procedures based upon accepted standards of practice.

4.8 Back-up power sufficient to ensure patient protection in the event of an emergency shall be immediately available.

4.9 There must be sufficient space in the room in which the procedure is being performed.

4.9.1 The room shall accommodate all necessary equipment and personnel allowing for expeditious access to the patient and all resuscitation and monitoring equipment.

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

4.11 A facility that chooses to stop performing invasive medical procedures and voluntarily surrenders accreditation**[~~,~~]** must notify the Department in writing, 30 days prior to the voluntary surrender of accreditation or cessation of invasive medical procedures.

## 5.0 Infection Control

5.1 The facility must provide and maintain a functional and sanitary environment**[~~,~~]** to avoid sources and transmission of infections and communicable diseases.

5.2 The facility shall establish and implement an ongoing infection prevention and control program which shall be based upon nationally-recognized infection control guidelines/standards (i.e. CDC, AORN, etc.) to prevent, control and investigate infections and communicable diseases.

5.2.1. The ongoing infection prevention and control program must:

5.2.1.1 Include an active surveillance component that covers both patients and personnel working in the facility.

5.2.1.1.1 Surveillance includes infection detection through ongoing data collection and analysis.

5.2.1.2 Include mechanisms that result in immediate action to take preventive or corrective measures that improve the facility's infection control outcomes.

5.2.1.3 Target its plan to 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.

**6.0 Medical Record**

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

6.2 The medical record must include:

6.2.1 Patient identifying information;

6.2.2 Patient's medical history and a physical examination:

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

6.2.2.2 Completed within 30 days prior to the procedure;

6.2.3 Diagnosis and plan of care;

6.2.4 Appropriate diagnostic reports;

6.2.5 Informed consent;

6.2.6 Documentation of the time-out;

6.2.7 Operative/procedure report**[;]**

6.2.8 Pathology reports, if applicable; **[~~and~~]**

6.2.9 Outcome and follow-up plans**[;]**

6.2.10 **[~~Documentation of anesthesia used:~~ A separate anesthesia record for each administration of anesthesia which must include:]**

**[~~6.2.10.1 A separate anesthesia record must be kept for all anesthesia/sedation;~~**

**~~6.2.10.2 Documentation must include:~~]**

6.2.10.**[~~2.~~]**1 Type of anesthesia;

6.2.10.**[~~2.~~]**2 Drug type, dose and route;

6.2.10.**[~~2.~~]**3 Time of administration;

6.2.10.**[~~2.~~]**4 Fluids administered;

6.2.10.**[~~2.~~]**5 Patient weight;

6.2.10.**[~~2.~~]**6 Vital signs monitoring;

6.2.10.**[~~2.~~]**7 Estimated blood loss;

6.2.10.**[~~2.~~]**8 Duration of procedure; and

6.2.10.**[~~2.~~]**9 Any complication or unusual event related to the procedure or anesthesia.

6.2.11 Intra-procedure and post-procedure monitoring.

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

**7.0 Patient Rights**

7.1 The facility must post written notice of patient rights in a conspicuous place, at or near**[~~,~~]** the entrance in a manner which is plainly visible and easily read by the patients (or their representatives, if applicable) waiting for treatment.

7.1.1 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.

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

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

7.2 The patient has the right to:

7.2.1 High-quality care delivered in a safe, timely, efficient and cost-effective manner and assurance the expected results can be reasonably anticipated.

7.2.2 Dignity, respect and consideration of legitimate concerns.

7.2.3 Privacy and confidentiality.

7.2.4 Be involved in all aspects of care:

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

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

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

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

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

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

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

7.2.10 Receive care from individuals who are properly trained and competent to perform their duties.

7.2.11 Request and receive a copy of the posted written notice of the patient rights.

## 8.0 Disciplinary Actions

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

8.1.1 Violated any of these regulations;

8.1.2 Violated standards for safe and sanitary care in a facility;

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

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

8.1.5 Refused to allow the Department access to the facility or records for the purpose of conducting inspections/surveys/investigations as deemed necessary by the Department based on the receipt of a complaint or report of an adverse event.

8.2 Disciplinary sanctions:

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

8.2.1.1 If the Department determines during the course of any investigation or inspection that any facility poses an immediate and 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.

8.2.1.1.1 An order of closure under this section shall remain in effect for a period not longer than 90 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.

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

8.2.1.2.1 Issue of a letter of reprimand and/or

8.2.1.2.2 Require the facility to complete a plan of correction.

8.3 Imposition of Disciplinary Action

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

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

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

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

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

8.3.3 In response to the order to close, the facility may:

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

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

8.3.3.2.1 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.

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

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

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

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

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

8.3.3.3.1.1 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.

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

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

8.3.3.3.2 A facility may request an expedited hearing.

8.3.3.3.2.1 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.

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

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

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

8.3.4 During an administrative hearing:

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

8.3.4.2 All statements made shall be under oath.

8.3.4.3 The facility has the right to examine and cross-examine witnesses.

8.3.4.4 A stenographic recording will be made by a qualified court reporter. At the request and expense of any party, such record shall be transcribed with a copy to the other party.

8.3.4.5 The decision of the Department shall be based upon sufficient legal evidence. If the charges are supported by such evidence, the Department may continue, modify or revoke the closure order.

8.3.5 Upon reaching its conclusion of law and determining an appropriate disciplinary action, the Department shall issue a written decision and order in accordance with § 10128 of Title 29.

8.3.6 All decisions of the Department shall be final and conclusive. Where the facility is in disagreement with the action of the Department, the facility may appeal the Department's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the facility. The appeal shall be on the record to the Superior Court and shall be as provided in §§ 10142 - 10145 of Title 29.

## 9.0 Accreditation Requirements and Procedures

9.1 General requirements

9.1.1 All facilities must register with the Department using a form created by the Department. It will include:

9.1.1.1 The facility name;

9.1.1.2 Facility address;

9.1.1.3 Facility phone number;

9.1.1.4 A contact person; and

9.1.1.5 Acknowledgment that invasive medical procedures are performed in the facility.

9.1.2 No person shall establish, conduct or maintain in this State any facility without obtaining accreditation from an accrediting organization that is approved by the Department.

9.1.2.1 The Department shall maintain a list of approved accrediting organizations.

9.1.3 All facilities must provide proof of accreditation to the Department within 12 months of the first day of operation of such facility.

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

9.1.5 The facility must submit an accreditation certificate to the Department within 30 days of each accrediting organization survey.

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

9.1.5.2 Facilities required to submit a plan of correction to an accrediting organization will also be required to submit a copy of the plan of correction to the Department.

9.2 Accreditation termination

9.2.1 Termination of accreditation may occur secondary to:

9.2.1.1 Voluntary surrender of accreditation by the facility.

9.2.1.2 Revocation of accreditation by the accrediting organization.

9.2.2 Any facility that fails to maintain accreditation shall immediately cease to operate.

9.2.2.1 The facility may be required to remain open for administrative purposes for a period of time to be determined by the Department.

9.3 Inspection

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

9.3.1.1 Anytime upon receipt of a complaint by a current facility employee or patient or upon the occurrence of any adverse event.

9.3.1.2 Anytime upon receipt of a referral from the Division of Professional Regulation.

9.3.2 Facilities certified by the Centers for Medicare and Medicaid Services (CMS) will be inspected pursuant to the process required by CMS rather than otherwise stated in these regulations.

9.4 Notice to patients

9.4.1 The 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.

9.4.2 The facility shall include in the notification information regarding alternative healthcare providers.

9.5 Exclusions from accreditation

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

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

**10.0 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.