DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF HEALTH CARE QUALITY
Division of Health Care Quality
3335 Office-Based Surgery

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 office-based surgery. 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.

23 DE Reg. 125 (08/01/19)

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 and all anesthesia, including local anesthesia, used for surgical abortions. For office-based surgery other than surgical abortions, the following shall be excluded from the definition of anesthesia: (1) local anesthesia, (2) the administration of less than 50% nitrous oxide in oxygen with or without local anesthesia but with no other sedative or analgesic medications by any route, or (3) the administration of a single, oral sedative or analgesic medication in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain with or without local anesthesia.

"**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 office-based surgery is performed, but does not include any hospital, as defined in 16 **Del.C.** §1001, or any freestanding birthing center, freestanding surgical center or freestanding emergency department as such terms are 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) the 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.

"**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.

"**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.

"**Musculoskeletal Injection**" means a trigger point injection, lumbar puncture, or injection that targets a joint, including shoulder, hip, knee, elbow, hand, wrist, foot, ankle, and sacroiliac joint. Musculoskeletal injections do not include any other injection in which the spine is the target of the injection.

"**Office-Based Surgery**" means any medical procedure, including dental and podiatric procedures, which include any of the following: (1) Surgical abortions, (2) Procedures in which the facility utilizes anesthesia, major conduction anesthesia or sedation, (3) Procedures in which the spine (i.e. epidural, facet joint) is the target of an injection, or (4) Procedures in which the accepted standard of care requires anesthesia, major conduction anesthesia or sedation. Office-based surgery does not include musculoskeletal injections.

"**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 office-based surgery.

"**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.

18 DE Reg. 862 (05/01/15)

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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;

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 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; or

4.5.2 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 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 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 office-based surgery and voluntarily surrenders accreditation must notify the Department in writing, 30 days prior to the voluntary surrender of accreditation or cessation of office-based surgery.

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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.

5.3 Specific Requirements for COVID-19

5.3.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Division of Public Health guidance.

5.3.2 All staff, vendors and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health guidance.

5.3.3 The facility must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.

5.4 The facility shall amend their policies and procedures to include:

5.4.1 Work exclusion and return to work protocols for staff tested positive for COVID-19;

5.4.2 Staff refusals to participate in COVID-19 testing;

5.4.3 Staff refusals to authorize release of testing results or vaccination status to the facility;

5.4.4 Procedures to obtain staff authorizations for release of laboratory test results to the facility to inform infection control and prevention strategies; and

5.4.5 Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

25 DE Reg. 770 (02/01/22)

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;

6.2.9 Outcome and follow-up plans;

6.2.10 A separate anesthesia record for each administration of anesthesia which must include:

6.2.10.1 Type of anesthesia;

6.2.10.2 Drug type, dose and route;

6.2.10.3 Time of administration;

6.2.10.4 Fluids administered;

6.2.10.5 Patient weight;

6.2.10.6 Vital signs monitoring;

6.2.10.7 Estimated blood loss;

6.2.10.8 Duration of procedure; and

6.2.10.9 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 office-based surgery.

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.

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9.0 Accreditation Requirements and Procedures

9.1 General requirements

9.1.1 All facilities must register with the Department at least 15 days prior to the first day of operation 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 office-based surgery is 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.

9.1.6 The accreditation organization shall report to the Department, at a minimum, all of the following regarding facilities the organization has accredited:

9.1.6.1 The findings of surveys;

9.1.6.2 The findings of complaint and incident investigations; and

9.1.6.3 Data for all facilities that perform office-based surgery.

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 office-based surgery 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**.

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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.

17 DE Reg. 848 (02/01/14)

18 DE Reg. 862 (05/01/15)

23 DE Reg. 125 (08/01/19)

25 DE Reg. 770 (02/01/22)