

28 Pa. Code § 555.31(a) Principle (Anesthesia Services - Propofol)

Structured Exception

The Department permits, through exception approval, the use of Propofol for sedation of patients undergoing surgical treatment in Class B ambulatory surgical facilities (ASFs).

Clinical evidence/support for this exception

The Department's current regulations include a classification system that identifies three levels of ambulatory surgery facilities (Class A, Class B, and Class C) based on the procedure, patient status, and anesthesia used. 28 Pa Code § 551.3 Definitions establish that Class B facilities offer surgical treatments involving administration of sedation analgesia or dissociative drugs wherein reflexes may be obtunded.

Propofol is the generic name for a general sedative drug also available as the brand name Diprivan.

The Department's "Guidance on Propofol use in Class B ASF", used in the past to outline conditions that must be met by the facility, is now incorporated into this guidance document. Facilities that are granted this exception will be on a one (1) year probationary period. After one year, the Department will evaluate the facility's use of Propofol. If the Department is satisfied with the facility's safe use of Propofol, the Department will grant the facility a non-probationary exception with conditions. After the Department grants the non-probationary exception with conditions, they will continue to monitor the safe use of Propofol. The Department will rescind the exception if concerns are identified.

Minimum requirements for this Propofol exception

- Propofol will be administered only for sedation.
- Propofol can only be used with PSI and PSII level patients.
- No general anesthesia is to be administered at the Class B facility.
- Only a Certified Registered Nurse Anesthetist (CRNA) or anesthesiologist with training and experience in the management of general anesthesia and credentialed by the facility shall administer Propofol. In addition, the CRNA or anesthesiologist must be trained on the use of Propofol, complications, and special need of the patient population.
- Propofol must be used according to package instructions.
- The CRNA or anesthesiologist administering the Propofol shall be qualified to rescue patients from any and all levels of sedation or anesthesia.
- The facility must have the essential equipment readily available for patient rescue as well as effective patient monitoring devices to include capnography.

- The CRNA and/or anesthesiologist must not only be dedicated to the task during administration of Propofol but must also be present throughout the entire procedure and until the patient is no longer at risk for cardiorespiratory depression.
- The CRNA and/or anesthesiologist must also maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression.
- ALL clinical staff involved in patient care must be ACLS certified.
- The facility must conduct unannounced quarterly safety drills related to adverse action to Propofol. These drills must include airway rescue scenarios as well as traditional ACLS cardiovascular scenarios that gauge staff's ability to urgently locate the equipment and ensure that the equipment is working properly.
- The facility must document the safety drills and develop a method to evaluate the team's performance during the safety drills and incorporate any identified areas into the facility's Quality Improvement Plan. At a minimum, documentation must include the date, time, participants, event details, and an assessment of the drill.
- The facility is required to maintain an adequate oxygen supply at all times to support all procedures as well as any emergencies that shall arise.
- Facility must adhere to Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018 Emergency Equipment for Sedation and Analgesia (<http://anesthesiology.pubs.asahq.org/article.aspx?articleid=2670190>) and be served by a Type 1 or Type 2 Essential Electric System in accordance with the National Fire Protection Association's Health Care Facilities Code, 2012 Edition.
- Facility must be registered with the Pennsylvania Patient Safety Authority and report the required information under the Act 13 known as MCARE Act.

Documentation to be provided to the Department by the facility:

- Policies and procedures reflecting minimum requirements described above.
- Proof of registration with the Patient Safety Authority.