



## **28 Pa. Code § 555.31(a) Anesthesia Services**

### **Approved Expedited Exception**

The Department permits 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 establishes 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 sedative drug also available as the brand name Diprivan.

Over the past 10 years the department has granted exceptions to 555.31(a) to permit the use of propofol in class B ASFs. The earliest requests for this exception were granted to endoscopy centers. As of August 1, 2014 Department records indicate this exception to 555.31(a) has been granted to 79 facilities. The Department is not aware of any reports of actual or potential harm to patients resulting from administration of propofol for sedation in ambulatory surgical facilities in this Commonwealth.

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. the facility to

### **Minimum requirements for this exception**

- Propofol will be administered only for sedation.
- No general anesthesia is to be administered at the Class B facility.
- Only a CRNA or anesthesiologist with training and experience in the management of general anesthesia and credentialed by the facility shall administer the propofol.
- The CRNA or anesthesiologist administering the propofol shall be qualified to rescue patients from any level of sedation, including general anesthesia.
- The facility must have equipment necessary for patient rescue readily available at all times.
- A facility seeking initial licensure must request an expedited exception to 551.31(a) within 48 hours of state licensure in order to avoid citation by the department's surveyors.

### **Documentation to be provided to the Dept by the facility:**

- Policies and procedures reflecting minimum requirements described above.

Approved 9.17.14

Amended 3.12.15