

**Facility Requesting Exception** \_\_\_\_\_  
**Facility Street Address** \_\_\_\_\_  
**Facility Contact Name** \_\_\_\_\_  
**Contact Mailing Address** \_\_\_\_\_  
**Contact Email Address** \_\_\_\_\_  
**Contact Phone Number** \_\_\_\_\_ **Facility License #** \_\_\_\_\_  
**Surveyor Name** \_\_\_\_\_

Please provide name and address for each facility to which the exception will be applied.

**Specific regulation for which the facility is requesting a Structured Exception:**

- 28 Pa. Code §107.2 Medical Staff Membership
- 28 Pa. Code §107.62(a) Oral Orders (b) Medical Staff By-laws
- 28 Pa. Code §123.25(2) Control of Anesthetic Explosion Hazards
- 28 Pa. Code §127.32 Written Orders (Radiology Services)
- 28 Pa. Code §555.32(a) Administration of Anesthesia (CRNA Students)
- 28 Pa. Code §569.35(7) General Safety Precautions (flammable agents in ASF)
- 28 Pa. Code §555.31(a) Anesthesia Services (Propofol)

**I am submitting the following documents required by the Department for consideration of this request:  
(list all required documents using document title)**

**YOU MUST INCLUDE A COMPLETED CHECKLIST WITH  
YOUR STRUCTURED EXCEPTION REQUEST**

\_\_\_\_\_  
**\*Signature of individual appointed by the Governing Body**

\_\_\_\_\_  
**Printed Name of individual appointed by the Governing Body**

\_\_\_\_\_  
**Title**

**\*The person appointed by the Governing Body of the facility who is responsible for the management & operations of the facility must sign the Exceptions Request form.**

**All DAAC Exception requests must be submitted as PDF documents to: [ra-paexcept@pa.gov](mailto:ra-paexcept@pa.gov)**

## **Checklist for Structured Exception**

### **28 Pa. Code §107.2 Medical Staff Membership (admit podiatrists to the medical staff of the hospital)**

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

Medical staff bylaws

## Checklist for Structured Exception

### 28 Pa. Code §107.62 (a,b) Oral Orders (verbal orders)

#### Documentation to be provided to the Department by the facility:

Written policy specific to oral orders that includes and reflects all regulatory requirements and all the hospital's procedures pertaining to oral orders, including time requirement for counter signature of the issuing physician.

Written policy specific to sound-alike drugs and the use of oral orders

Process for monitoring and tracking the incidence of oral orders

Medical staff bylaws must specify the personnel qualified to accept oral orders

Copy of appropriate section of medical staff bylaws

## **Checklist for Structured Exception**

**28 pa. Code §123.25 (2) Control of Anesthetic Explosion Hazards**  
**28 Pa. Code §569.35 (7) Non Flammable Agents in Surgical Suite**

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

Hospital or ASF policies and procedures for use of skin preparation solutions that contain combustible agents, including:

Procedures for use of skin preparations that contain combustible agents in surgical settings where electrocautery, laser or other sources of ignition may be present in order to reduce the risk of fire associated with the use of combustible skin preparations.

Content and documentation of annual mandatory education provided to all staff, including the physician staff, involved in the use of surgical skin preparations that contain combustible agents.

Documentation of notification to the facility's general liability carrier regarding use of surgical skin preparations that contain combustible agents any response by the insurance carrier.

## Checklist for Structured Exception

### 28 Pa. Code §127.32 Written Orders (Radiology Services)

#### Documentation to be provided to the Department by the facility:

Approved policy for authorizing practitioners who are not on the medical staff to order outpatient diagnostic radiology services.

The approval process must include assurance that the practitioner:

Possesses a current valid PA professional license

Is authorized by PA professional licensure statute and/or regulation to order diagnostic radiology services

Has professional liability insurance, if appropriate

## **Checklist for Structured Exception**

### **28 Pa. Code §555.32(a) Administration of Anesthesia (CRNA Students)**

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

A signed affiliation agreement between the facility and the nurse anesthesia education program or school setting forth the terms and conditions of student clinical training in that facility. If the affiliation agreement is an umbrella agreement covering multiple sites within a healthcare system, it must specifically name the ASF as a clinical teaching site.

Evidence of the education program's/school's current valid COA accreditation.

## Checklist for Structured Exception

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

#### Documentation to be provided to the Department by the facility:

##### Policies and procedures reflecting minimum requirements:

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.