

State Regulatory Environment Overview: “Office-Based Surgery”

Frequently Asked Questions (FAQ)

Office-Based Surgery

The advancement of technology, paired with patient comfort and convenience of the physician office, has resulted in a shift in where many surgical procedures are currently performed. Many surgical procedures once performed solely in a hospital outpatient facility or ambulatory surgical center setting are now being performed in the physician’s office. This shift in site-of-service may provide savings to the healthcare system while increasing patient comfort and convenience, and allows for physician ease of scheduling. It also creates a need for quality and safety standards and measures.

As a service to our customers, Boston Scientific has prepared this FAQ to address some of the more commonly asked questions related to office-based surgery and the growing state regulatory environment.

Questions & Answers

What is Office-Based Surgery?

Office-based surgery is any surgical procedure performed by a licensed physician in the office setting, requiring some level of anesthesia.

How are levels of anesthesia defined?

The American Society of Anesthesiologists (ASA) defines the various levels of anesthesia (sedation) as follows:

- **Level 1 - Minimal sedation (anxiolysis)**
A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
- **Level 2 - Moderate sedation (“Conscious Sedation”)**
A drug-induced depression of consciousness during which patients respond purposefully¹ to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- **Level 3 - Deep sedation/Analgesia**
A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully¹ following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- **Level 4 – General Anesthesia**
A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. Spontaneous Ventilation is frequently inadequate and cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia. The complete ASA guideline “**Continuum of Depth of Sedation Definition of General Anesthesia and Levels of Sedation/Analgesia**” may be found at www.asahq.org/publicationsAndServices/standards/20.pdf

¹Reflex withdrawal from a painful stimulus is NOT considered a purposeful response

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My practice uses para-cervical block and Ketorolac Trometramine IM for several office-based surgeries. What level of anesthesia does this fall under?

This would be considered mild sedation under the ASA guidelines and therefore, fall into Level I anesthesia.

My practice uses conscious sedation for several office-based surgeries. What level of anesthesia does this fall under?

Conscious sedation is considered moderate sedation under ASA guidelines and would be considered Level II anesthesia.

Does the AMA have guidelines for office-based surgery?

Yes. The AMA has established a set of “*Office-based Surgery Core Principles*” which were developed to assist legislative, regulatory, and/or administrative bodies that may become involved in setting standards for office-based surgery. According to the AMA, the core principles “...represent a wide consensus within the medical profession...” and “...are intended to be used collectively to promote consistency in the safety and quality of healthcare services for in-office procedures requiring moderate sedation, deep sedation, or general anesthesia.” The complete AMA guideline “*Office-based Surgery Core Principles*” may be found at

www.ama-assn.org/ama1/pub/upload/mm/370/obscoreprinciples.pdf.

Do the AMA guidelines advocate facilities performing office-based surgery (OBS) become accredited?

Core Principle #3 of the AMA Office-based Surgery Core Principles states that offices performing procedures requiring moderate sedation or above should have their facilities accredited.

Who are the nationally recognized accreditation organizations?

There are several nationally recognized accreditation organizations. Below are a few, including a link to their website where you can obtain additional information:

- **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)** - www.jointcommission.org
- **Accreditation Association for Ambulatory Health Care (AAAHC)** - www.aaahc.org
- **American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF)** - www.aaaasf.org

Why are states creating regulations for surgical services performed in an office setting?

In an effort to promote the safety and quality of healthcare services for surgical procedures performed in an office setting many states have implemented regulations. These regulations require state-specific criteria be met by physicians' offices in order to perform certain surgical procedures in the office setting.

Are regulations similar across all states?

No. Regulations vary by state, with some states sharing similar criteria. A number of states follow the AMA guidelines and require a physician's office be accredited by a nationally recognized accreditation agency when performing surgical procedures requiring Level II anesthesia (moderate sedation or “conscious sedation”) or higher.