BOARD OPINION
RELATING TO OFFICE-BASED SURGERY

LEGAL AUTHORITY

Pursuant to KRS 311.602, the Board renders the following opinion to assist Board licensees in determining what actions would constitute unacceptable conduct under the provisions of KRS 311.595. The Board has decided to publish this opinion because it addresses issues of significant public and medical interest.

ACCEPTABLE AND PREVAILING MEDICAL PRACTICES OF OFFICE-BASED SURGERY

I. STATEMENT OF INTENT AND GOALS

The Board rendered this opinion to promote patient safety in the non-hospital setting during procedures that require the administration of conscious sedation, local, or general anesthesia, or minor or major conduction blockade. Moreover, this opinion is published to provide physicians performing office-based surgery, (including cryosurgery and laser surgery), that requires anesthesia (including tumescent anesthesia), analgesia or sedation a summary of what, in the Board's opinion, constitutes the acceptable and prevailing medical practices and principles. Minor procedures in which unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer's recommended dose, adjusted for weight, are excluded from this opinion. Nonetheless, it is the acceptable and prevailing medical practice that any practice performing office-based surgery regardless of anesthesia have the necessary equipment, protocol, and personnel to handle emergencies resulting from the procedure and/or anesthesia.

It is the Board's opinion that the following principles constitute the standards of acceptable and prevailing medical practice relating to the delivery of office-based surgery. In making this determination, the Board has considered relevant statutes (cited where appropriate), practice standards relating to physicians' conduct and interactions with other health care professionals and basic practice standards.

II. DEFINITIONS

For purposes of this opinion, the following terms are defined as follows:

A. *"Advanced cardiac life support trained"* means that a licensee has successfully completed and requalified periodically an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (APLS) is appropriate.

B. *"Anesthesiologist"* means a physician who has successfully completed a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

C. *"Anesthetizing location"* means any location in an office where anesthetic agents are administered to a patient.

D. *"Board"* means the Kentucky Board of Medical Licensure.

E. *"Complications"* means an untoward event occurring at any time within 48 hours of surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than 24 hours, or death.

F. *"Deep sedation/analgesia"* means the administration of a drug or drugs which produces depression of consciousness during which patients cannot be easily aroused but respond purposefully 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.

G. *"General anesthesia"* means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. 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. Cardiovascular function may be impaired.

H. *"Hospital"* means a hospital licensed by the state in which it is situated.

I. *"Local anesthesia"* means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

J. *"Major surgery"* means surgery that requires moderate sedation, deep sedation, general anesthesia, or major conduction blockade for patient comfort.

K. *"Major conduction blockade"* means the injection of local anesthesia to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, blocks of the upper extremity or lower extremity or neuraxial blocks.

L. *"Minimal sedation" (anxiolysis)* means the administration of a drug or drugs which produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function should remain unaffected and defensive airway reflexes should remain intact.

M. *"Minor surgery"* means surgery that can be safely and comfortably performed on a patient who has received local or topical anesthesia, without more than minimal pre-operative medication or minimal intraoperative sedation and where the likelihood of complications requiring hospitalization is remote.

N. *"Minor conduction block"* means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, infiltration or local nerve block), including the block of a nerve by direct pressure and refrigeration. Minor conduction blocks, like local infiltration, are typically performed by the operating physician and involve smaller areas or distal nerves.

O. *"Moderate sedation/analgesia"* means the administration of a drug or drugs which produces depression of consciousness during which patients respond purposely to verbal commands, either alone or accompanied by a light tactile stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

P. *"Monitoring"* means continuous visual observation of a patient and documentation of the patient's status as deemed appropriate by the level of sedation or recovery using instruments to measure, display and record physiologic values such as heart rate, blood pressure, respiration and oxygen saturation.

Q. *"Office"* means a location at which medical or surgical services are rendered.

R. *"Office-Based Surgery"* means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, including cryosurgery and laser surgery, which results in patient stay of less than 24 consecutive hours and is performed by a physician in a location other than a hospital or a diagnostic treatment center, including free-standing ambulatory surgery centers.

S. *"Operating room"* means that location in the office dedicated to the performance of surgery or special procedures.

T. *"Physical status classification"* means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists enumerates the following classifications: I – Normal, healthy patient; II – A patient with mild systemic disease; III – A patient with severe systemic disease limiting activity but not incapacitating; IV – A patient with incapacitating systemic disease that is a constant threat to life; and V – Moribund patients not expected to live 24 hours with or without operation.

U. *"Physician"* means an individual holding an M.D. or D.O. degree licensed pursuant to the Kentucky Medical and Osteopathic Practices Act.

V. *"Recovery area"* means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

W. *"Special procedure"* means patient care which requires entering the body with instruments in a potentially painful manner, or which requires the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; for example, diagnostic or therapeutic endoscopy, invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia or endoscopic examination with the use of general anesthetic.

X. *"Surgery"* means any operative or manual procedures, including the use of lasers as used under the direction of a physician in certain cases, performed for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or reliving suffering, or any elective procedure for aesthetic or cosmetic purposes. This includes, but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; extraction of tissue from the uterus; insertion of natural or artificial implants; closed or open fracture reduction; or an endoscopic examination with use of local or general anesthetic.

Y. *"Topical Anesthesia"* means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

III. OFFICE ADMINISTRATION

A. Periodic Review of Applicable Laws

In the Board's opinion, it is the acceptable and prevailing medical practice that the medical director or governing body should ensure that all applicable local, state and federal regulations are observed and that all written policies and procedures are subject to periodic review and updating.

B. Written Policies, Protocols and Procedures

Written policies and procedures can assist office-based practices in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients. The following eight (8) areas are important aspects of an office-based practice that should benefit from simple policy and procedure statements:

1. Quality of Care: Pre-Operative Evaluation of Patient for risk assessment using ASA criteria and determination that procedure is within the scope of

practice of the health care practitioners and the capabilities of the facility. A time out should be performed prior to initiation of a procedure.

2. Discharge Protocols, including on-site monitoring until the patient returns to pre-anesthesia baseline(s)

3. Emergency Care and Transfer Plan

   It is the acceptable and prevailing medical practice to have a plan in place that provides for emergency medical care as well as the safe and timely transfer of patients to a nearby hospital should hospitalization be necessary and which includes the following:

   - Age-appropriate emergency supplies, equipment and medication in accordance with the scope of surgical and anesthesia services provided at the physician's office.

   - In an office where anesthesia services are provided to infants and children, required emergency equipment appropriately sized for a pediatric population, and personnel appropriately trained to handle pediatric emergencies (APLS or PALS certified).

   - A physician who is qualified in resuscitation techniques and emergency care should be present and available until all patients having more than local anesthesia or minor conductive block anesthesia have been discharged from the office (Advanced adult or pediatric life support certified).

   - In the event of untoward anesthetic, medical or surgical complications or emergencies, the physician should be familiar with the procedures and plan to be followed, and able to take the necessary actions. A documented plan for the timely and safe transfer of patients to a nearby hospital should be in place and include arrangements for emergency medical services, if necessary, or escort of the patient to the hospital by an appropriate physician. If advanced cardiac life support is instituted, the plan should include immediate contact with emergency medical services.

4. Medical Record Maintenance and Security

   It is the acceptable and prevailing medical practice to have a procedure for initiating and maintaining a health record for every patient evaluated or treated and that each record include a procedure code or suitable narrative description of the procedure and sufficient information to identify the patient, support the diagnosis, justify the treatment and document the outcome and required follow-up care. It is important to document the names of providers and ancillary personnel. For procedures requiring patient consent, it is the

acceptable and prevailing medical practice to obtain and maintain documented informed written consent. If analgesia/sedation, minor or major conduction blockade or general anesthesia are provided, it is the acceptable and prevailing medical practice to include documentation of the type of anesthesia used, drugs (type and dose) and fluids administered, the record of monitoring of vital signs, level of consciousness during the procedure, patient weight, estimated blood loss, duration of the procedure, and any complications related to the procedure or anesthesia. In addition, it is the acceptable and prevailing medical practice to maintain procedures that assure patient confidentiality and security of all patient data and information.

5. Infection Control Policy

   It is the acceptable and prevailing medical practice to comply with state and federal regulations regarding infection control, sterilization, and disposal of hazardous waste products.

6. Performance Improvement

   It is the acceptable and prevailing medical practice to review at least every six (6) months the current practice activities and quality of care provided to patients, including peer review by members not affiliated with the same practice.

   It is the acceptable and prevailing medical practice to establish a performance improvement (PI) program for office-based surgery. This PI program could be created by the practice itself or could come from a cooperative agreement with established PI programs produced by another practice, a hospital, a medical specialty society or other peer review organization. This program should be documented in writing and periodically reviewed by the practice. (As an example, see Appendix IV, *Safety Checklist for Office-Based Surgery* developed by the Institute for Safety in Office-Based Surgery.)

7. Federal and State Laws and Regulations

   It is the acceptable and prevailing medical practice to identify and comply with federal and state laws and regulations that affect the practice.

8. Patients' Bill of Rights

   It is the acceptable and prevailing medical practice to recognize the basic rights of patients and understand the importance of maintaining patients' rights.

IV. STANDARDS FOR OFFICE PROCEDURES

A. Physician

It is the acceptable and prevailing medical practice that a physician only perform surgical procedures and anesthesia services that are commensurate with the physician's level of training and experience.

B. Training

It is the acceptable and prevailing medical practice that the physician pursue continuing medical education in proper drug dosages, management of toxicity or hypersensitivity to local anesthetic and other drugs. The physician should obtain and maintain Advanced Cardiac Life Support certification. If the physician is performing office-based procedures involving pediatric patients, it is the acceptable and prevailing medical practice that the physician obtain and maintain Pediatric Advanced Life Support (PALS) (or other profession specific equivalent training).

C. Equipment and supplies

It is the acceptable and prevailing medical practice that emergency resuscitation equipment, suction, a reliable source of oxygen, positive pressure ventilation device, and all medications from the ACLS, PALS and MH as per national protocols be immediately available as appropriate to the patient, practice and anesthesia used. It is the acceptable and prevailing medical practice that monitoring during the office procedure include pulse oximeter, blood pressure measurement (NIBP) and cardiac monitoring as appropriate for the patient and procedure. Age-appropriate monitors and resuscitative equipment should be available for pediatric patients. Monitoring in a recovery area should include continuous cardiac monitoring, use of pulse oximetry and NIBP devices. A cardiac defibrillator/AED with appropriate pads should be available.

D. Assistance of Other Personnel

It is the acceptable and prevailing medical practice that a physician providing supervision should:

- Assure that an appropriate preanesthetic examination and evaluation is performed proximate to the procedure;
- Prescribe the anesthesia;
- Assure that qualified practitioners participate;
- Remain physically present during the entire perioperative period and immediately available for diagnosis, treatment, and management of anesthesia-related complications or emergencies; and

- Assure the provision of indicated post-anesthesia care.

E. Time Out

It is the acceptable and prevailing medical practice that the physician ensure that a time-out is observed immediately prior to surgical incision, during which time activities are suspended (to the extent possible) and team members actively confirm the patient, site and procedure.

F. Discharge Criteria

The patient should be assessed regularly for level of consciousness, pain relief, nausea, vomiting or any untoward complication. Each patient should meet discharge criteria (to include a return to pre-anesthesia baseline) as established by the practice, prior to leaving the facility.

G. Transfer and Emergency Protocols

It is the acceptable and prevailing medical practice that the surgeon has a *written* transfer protocol in effect with a hospital within reasonable proximity for cardiopulmonary and other medical or surgical emergencies as well as other internal and external disasters such as fire or electrical outage.

V. PATIENT ADMISSION AND DISCHARGE

A. Patient Selection

It is the acceptable and prevailing medical practice that the physician evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is responsible for determining that the patient has an adequate support system to provide for necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at risk for complications, should be referred to an appropriate specialist for pre-operative consultation.

It is the acceptable and prevailing medical practice that patients, who are considered high risk, have unstable medical problems, are ASA physical status classification III or greater, have anticipated airway difficulty, or require a general anesthetic for the surgical procedure, have the procedure performed in a hospital setting.

Acceptable candidates for an office-based surgical procedure requiring deep sedation, general anesthesia, or major conduction blockade are typically those patients with an ASA physical status classification of I or II, no airway abnormality, and an unremarkable anesthetic and surgical history.

B. Informed Consent

It is the acceptable and prevailing medical practice that the risks, benefits, and potential complications of both the surgery and anesthetic be discussed with the patient and/or, if applicable, the patient's legal guardian prior to the surgical procedure. Written documentation of informed consent should be included in the medical record.

C. Preoperative Assessment

It is the acceptable and prevailing medical practice that a medical history and physical examination be performed, and appropriate laboratory studies obtained within 30 days of the planned surgical procedure, by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. In addition, it is the acceptable and prevailing medical practice that a preanesthetic examination and evaluation should be conducted immediately prior to surgery by the physician, who will be administering or supervising the anesthesia. The information and data obtained during the course of these evaluations should be documented in the medical record.

D. Discharge Evaluation

It is the acceptable and prevailing medical practice that the physician who administered or supervised the anesthesia evaluate the patient immediately upon completion of the surgery and anesthesia and prior to transferring care of the patient. A physician should remain immediately available until the patient meets discharge criteria.

Criteria for discharge for all patients who have received anesthesia include the following:

- Confirmation of stable vital signs
- Stable oxygen saturation levels
- Return to pre-anesthesia baseline(s), including mental status
- Adequate pain control
- Minimal bleeding nausea and vomiting
- Resolving neural blockade, resolution of the neuraxial blockade
- Discharged in the company of a competent adult

E. Patient Instructions

It is the acceptable and prevailing medical practice that the patient be given verbal instruction understandable to the patient or guardian and written post-operative instructions and emergency contact numbers.

The instructions should include the following information:

- The procedure performed;
- Information about potential complications;
- Telephone numbers to be used by the patient to discuss complications or should questions arise;
- Instructions for medications prescribed and pain management;
- Information regarding the follow-up visit date, time and location; and
- Designated treatment facility in the event of emergency.

Published as Board Opinion on June 16, 2011; amended March 15, 2018 and December 18, 2025.

Appendix I

Sample Patient Bill of Rights

1. The patient has the right to high quality health care delivered in a safe and efficient manner.

2. The patient has a right to dignity and respect.

3. The patient has a right to privacy, confidentiality, and consideration of any legitimate concerns.

4. The patient has a right to know his or her diagnosis, treatment options and prognosis.

5. The risks, benefits, and possible complications of each treatment or procedure need to be addressed.

6. The patient has the right to know the qualifications of individuals who will be participating in their care.

7. The patient has the right to refuse treatment and be advised of the consequences of this decision.

8. The patient has a right to inspect and obtain a copy of his or her medical records.

9. Charges to the patient to obtain the medical record should not be excessive.

10. The patient has a right to inspect and obtain information regarding the billing services.

11. The patient has a right to request information regarding alternative appropriate care.

12. The patient has a right to know the expectations of his or her behavior and the consequences of not complying with these expectations.

Appendix II
Major Accrediting Agencies

American Association for Accreditation of Ambulatory Surgical Facilities, Inc.
(AAAASF)
1202 Allanson Road
Mundelein, IL 60060
(847)949-6058

Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)
9933 Lawler Avenue
Skokie, IL 60077-3702
(847)676-9610

Joint Commission on Accreditation of HealthCare Organizations (JCAHO)
One Renaissance Boulevard
Oak Brook Terrace, IL 60181
(630)916-5600

Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Administrator, Health Care Financing Administration
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201
(202)690-6726

Appendix III

Useful Administrative Information

A. Occupational Safety and Health Administration (OSHA)
OSHA is a division of the US Department of Labor and is responsible for the enforcement of the health and safety guidelines set forth in the OSHA Act of 1970. Practices are subject to OSHA Hazard Communications Standard of 1987 and the Blood Borne Pathogen Standard 29 CFR 1910 1030. Both standards have very specific requirements and require written policy manuals and formal training regarding the standards. Other applicable OSHA standards include Access to Employee Exposure and Medical Records, and Personal Protective Equipment.

B. Americans with Disabilities Act
Copies may be obtained by calling the Equal Employment Opportunity Commission at 1-800-669-4000 or www.eeoc.gov

C. National Fire Protection Association-NFPA Life Safety Code
National Fire Protection Association
One Batterymarch Park
P.O. Box 9101
Quincy, MA 02269-9101
(617)770-4543

D. Codes of Ethical Business and Professional Behavior
American College of Surgeons
55 East Erie Street
Chicago, IL 60611-2797
(312)202-5000

E. American Society of Anesthesiologists
520 North Northwest Highway
Park Ridge, IL 60068-2573
(847)828-5586
www.asa.hq.org

F. American Medical Association
515 North State Street
Chicago, IL 60610
1-800-634-6922 or 1-800-621-8335

G. The American Association of Nurse Anesthetists
222 South Prospect Avenue
Park Ridge, IL 60068-4001
(847)698-7050
www.aana.com

Appendix IV

Safety Checklist for Office-Based Surgery

from the Institute for Safety in Office-Based Surgery (ISOBS)

Introduction
Preoperative encounter; with practitioner and patient

Patient

Patient medically optimized for the procedure?
☐ *Yes*
☐ *No, and plan for optimization made.*

Does patient have DVT risk factors?
☐ *Yes, and prophylaxis plans arranged.*
☐ *No*

Procedure

Procedure complexity and sedation/analgesia reviewed?
☐ *Yes*

NPO instructions given?
☐ *Yes*

Escort and post-procedure plans reviewed?
☐ *Yes*

Setting
Before patient in procedure room; with practitioner and personnel

Emergency equipment check complete (e.g. airway, AED, code cart, MH kit)?
☐ *Yes*

EMS availability confirmed?
☐ *Yes*

Oxygen source and suction checked?
☐ *Yes*

Anticipated duration ≤ 6 hours?
☐ *Yes*
☐ *No, but personnel, monitoring and equipment available*

Operation
Before sedation/analgesia; with practitioner and personnel*

Patient identity, procedure, and consent confirmed? ☐ *Yes*

Is the site marked and side identified?
☐ *Yes* ☐ *N/A*

DVT prophylaxis provided?
☐ *Yes* ☐ *N/A*

Antibiotic prophylaxis administered within 60 minutes prior to procedure? ☐ *Yes* ☐ *N/A*

Essential imaging displayed?
☐ *Yes* ☐ *N/A*

Practitioner confirms verbally:

☐ **Local anesthetic toxicity precautions**

☐ **Patient monitoring (per institutional protocol).**

☐ **Anticipated critical events addressed with team.**

☐ **Each member of the team has been addressed by name and is ready to proceed.**

Before discharge
On arrival to recovery area; with practitioner & personnel

Assessment for pain?
☐ *Yes*

Assessment for nausea/ vomiting?
☐ *Yes*

Recovery personnel available?
☐ *Yes*

Prior to discharge: (with personnel and patient)

Discharge criteria achieved?
☐ *Yes*

Patient education and instructions provided?
☐ *Yes*

Plan for post-discharge follow-up?
☐ *Yes*

Escort confirmed?
☐ *Yes*

Satisfaction
Completed post-procedure; with practitioner and patient

Unanticipated events documented?
☐ *Yes*

Patient satisfaction assessed?
☐ *Yes*

Provider satisfaction assessed?
☐ *Yes*

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. *Adapted from the WHO Surgical Safety Checklist.

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