The Texas Medical Board (Board) proposes the repeal of current Chapter 173, concerning Physician Profiles, §§173.1 – 173.5, and §173.7.

The Board also proposes new Chapter 173, concerning Office-Based Anesthesia Services, §§173.1 - 173.5.

Also, the Board contemporaneously proposes the repeal of current Chapter 192, concerning Office-Based Anesthesia Services, §§192.1 – 192.6.

The Board has determined that due to the extensive reorganization of Chapters 160-200, repeal of Chapter 173 is more efficient than proposing multiple amendments to make the required changes.

The proposed new sections are as follows:

New §173.1, General Definitions, defines terms used in new Chapter 173.

New §173.2, Standards for Anesthesia Services, explains the standards and minimum equipment requirements when providing anesthesia services in an outpatient setting.

New §173.3, Specific Requirements Based on Level of Anesthesia Provided, explains the additional standards applicable to outpatient settings based upon the level of anesthesia being provided in Level I, Level II, Level III, and Level IV anesthesia services.

New §173.4, Registration, explains the process in which a physician providing anesthesia services or performing a procedure for anesthesia services are provided in an outpatient setting (excluding Level I services) must register with the board.

New §173.5, Inspections, explains that the board may conduct inspections for the purpose of enforcing Office-Based Anesthesia rules.

Scott Freshour, General Counsel for the Texas Medical Board, has determined that, for each year of the first five years the proposed repeals and new sections are in effect, the public benefit anticipated as a result of enforcing these proposed sections will be to remove redundant language from rules, simplify the rules, and make the rules easier to understand.

Mr. Freshour has also determined that for the first five-year period these proposed repeals and new sections are in effect, there will be no fiscal impact or effect on government growth as a result of enforcing the proposed sections.

Mr. Freshour has also determined that for the first five-year period these proposed repeals and new sections are in effect there will be no probable economic cost to individuals required to comply with these proposed sections.

Pursuant to Texas Government Code §2006.002, the agency provides the following economic impact statement for these proposed repeals and new sections and determined that for each year of the first five years these proposed repeals and new sections will be in effect there will be no effect on small businesses, micro businesses, or rural communities. The agency has considered alternative methods of achieving the purpose of these proposed repeals and new sections and found none.

Pursuant to Texas Government Code §2001.024(a)(4), Mr. Freshour certifies that this proposal has been reviewed and the agency has determined that for each year of the first five years these proposed repeals and new sections are in effect:

(1) there is no additional estimated cost to the state or to local governments expected as a result of enforcing or administering these proposed repeals and new sections;

(2) there are no estimated reductions in costs to the state or to local governments as a result of enforcing or administering these proposed repeals and new sections;

(3) there is no estimated loss or increase in revenue to the state or to local governments as a result of enforcing or administering these proposed repeals and new sections; and

(4) there are no foreseeable implications relating to cost or revenues of the state or local governments with regard to enforcing or administering these proposed repeals and new sections.

Pursuant to Texas Government Code §2001.024(a)(6) and §2001.022, the agency has determined that for each year of the first five years these proposed repeals and new sections will be in effect, there will be no effect on local economy and local employment.

Pursuant to Government Code §2001.0221, the agency provides the following Government Growth Impact Statement for these proposed repeals and new sections. For each year of the first five years these proposed repeals and new sections will be in effect, Mr. Freshour has determined the following:

(1) These proposed repeals and new sections do not create or eliminate a government program.

(2) Implementation of these proposed repeals and new sections does not require the creation of new employee positions or the elimination of existing employee positions.

(3) Implementation of these proposed repeals and new sections does not require an increase or decrease in future legislative appropriations to the agency.

(4) These proposed sections do not require an increase or decrease in fees paid to the agency.

(5) These proposed repeals and new sections do not create new regulations.

(6) These proposed repeals and new sections do repeal existing regulations as described above. These proposed new sections do not expand or limit an existing regulation.

(7) These proposed repeals and new sections do not increase the number of individuals subject to the sections’ applicability.

(8) These proposed repeals and new sections do not positively or adversely affect this state's economy.

Comments on the proposal may be submitted using this link: https://forms.office.com/g/0JHZyixFBb. A public hearing will be held at a later date. Comments on the proposal will be accepted for 30 days following publication.

The repeal of the rules is proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to recommend and adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine; and enforce this subtitle. The repeal of the rules is also proposed in accordance with the requirements of Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for readoption, readoption with amendments, or repeal every four years. No other statutes, articles or codes are affected by this proposal.

<rule>

§173.1. Profile Contents.

§173.2. Profile Update and Correction Form.

§173.3. Physician-Initiated Updates.

§173.4. Updates to the Physician’s Profile Due to Board Action.

§173.5. Updates to the Physician’s Profile Due to Information Received by a Third Party.

§173.7. Corrections and the Dispute Process.

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The new rules are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to recommend and adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine; and enforce this subtitle. The new rules are also proposed under the authority of §162; and in accordance with the requirements of Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for readoption, readoption with amendments, or repeal every four years. No other statutes, articles, or codes are affected by this proposal.

<rule>

§173.1. General Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the contents indicate otherwise:

(1) ACLS--Advanced Cardiac Life Support, as defined by the AHA.

(2) AED--Automatic External Defibrillator.

(3) AHA--American Heart Association.

(4) Analgesics--Dangerous or scheduled drugs that alleviate pain, but not including non-opioid based drugs such as acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs).

(5) Anesthesia--Use of local anesthetics (in amounts that generate the effect of general anesthesia, regional anesthesia, or monitored anesthesia care), analgesics, anxiolytics, or hypnotics to create a loss of feeling or sensation by interrupting or depressing nerve function.

(6) Anesthesia Services--The use of anesthesia for the performance of Level II- IV services.

(7) Anxiolytics--Dangerous or scheduled drugs used to provide sedation or to treat episodes of anxiety.

(8) ASHI--American Safety and Health Institute.

(9) ASA--American Society of Anesthesiologists.

(10) BLS--Basic Life Support, as defined by the AHA.

(11) Certified registered nurse anesthetist (CRNA)--A person licensed by the Texas Board of Nursing (TBON) as a certified registered nurse anesthetist.

(12) Dangerous drugs--Medications defined by Chapter 483, Texas Health and Safety Code. Dangerous drugs require a prescription but are not included in the list of scheduled drugs. A dangerous drug bears the legend “Caution: federal law prohibits dispensing without a prescription” or “Prescription Only.”

(13) Hypnotics--Dangerous or scheduled drugs used to induce unconsciousness. This includes inhaled anesthetics and nonvolatile anesthetic agents such as Barbiturates, Benzodiazepines, Opioids, Etomidate, Propofol, and Ketamine.

(14) Level I services.

(A) Delivery of analgesics or anxiolytics by mouth, as prescribed for the patient on order of a physician, at a dose level low enough to allow the patient to remain ambulatory; or

(B) Delivery of nitrous oxide/oxygen inhalation sedation.

(15) Level II services.

(A) The administration of tumescent anesthesia;

(B) The delivery of analgesics or anxiolytics by mouth in dosages greater than allowed at Level I, as prescribed for the patient on order of a physician; or

(C) Except for the performance of Mohs micrographic surgery, the administration of local anesthesia, peripheral nerve blocks, or both in a total dosage amount that exceeds 50 percent of the recommended maximum safe dosage per outpatient visit.

(16) Level III services--Parenteral delivery of analgesics or anxiolytics.

(17) Level IV services--Delivery of general anesthetics, including regional anesthetics and monitored anesthesia care; spinal, epidural, or caudal blocks for the purposes of providing anesthesia or monitored anesthesia care.

(18) Local anesthetics--Dangerous drugs administered topically or by injection, which interrupt nerve conduction, temporarily creating a loss of sensation to an affected area and that generate the effect of general anesthesia, regional anesthesia, or monitored anesthesia care.

(19) Monitored anesthesia care--Includes all aspects of anesthesia care by an anesthesiologist or member of the anesthesia care team including the administration of sedatives, analgesics, hypnotics and other anesthesia agents or medications necessary to ensure patient safety and comfort. May include situations where a patient undergoing a diagnostic or therapeutic procedure receives doses of medication that create a risk of loss of normal protective reflexes or loss of consciousness and the patient remains able to protect the airway during the procedure. If the patient is rendered unconscious and loses normal protective reflexes, then anesthesia care shall be considered a general anesthetic.

(20) Outpatient setting--Any facility, clinic, center, office, or other setting that is not a part of a licensed hospital or a licensed ambulatory surgical center with the exception of the following:

(A) a clinic located on land recognized as tribal land by the federal government and maintained or operated by a federally recognized Indian tribe or tribal organization as listed by the United States secretary of the interior under 25 U.S.C. §479-1 or as listed under a successor federal statute or regulation;

(B) a facility maintained or operated by a state or governmental entity;

(C) a clinic directly maintained or operated by the United States or by any of its departments, officers, or agencies; and

(D) an outpatient setting where the facility itself is accredited by either The Joint Commission relating to ambulatory surgical centers, the American Association for Accreditation of Ambulatory Surgery Facilities, or the Accreditation Association for Ambulatory Health Care.

(21) PALS--Pediatric Advanced Life Support, as defined by the AHA.

(22) Peripheral nerve block--The injection of local anesthetics into an area of the body directly adjacent to a peripheral nerve, for the purpose of blocking the response to pain in the distribution of sensation of that nerve.

(23) Scheduled drugs--Medications defined by the Texas Controlled Substances Act, Chapter 481, Texas Health and Safety Code.

(24) Tumescent anesthesia--A specialized type of subcutaneous infiltration of a dilute mixture of local anesthetic and epinephrine known as tumescent solution.

§173.2. Standards for Anesthesia Services.

(a) General Standards. When providing anesthesia services in an outpatient setting, physicians must:

(1) comply with delegation and supervision laws under Chapter 157 of the Act, including §157.058, regarding CRNAs;

(2) counsel and prepare patients for anesthesia per ASA standards;

(3) perform:

(A) a pre-anesthetic evaluation; and

(B) a pre-sedation evaluation, that includes at a minimum an airway evaluation and an ASA physical status classification;

(4) obtain informed consent in accordance with state law, which includes communicating with the patient any sharing of responsibility for a patient's care with other physicians or non-physician anesthesia providers; and

(5) provide continuous appropriate physiologic monitoring of the patient, determined by the type of anesthesia and individual patient needs, both during and post procedure until ready for discharge, with continuous monitoring of

(A) ventilation,

(B) oxygenation; and

(C) cardiovascular status.

(b) Minimum Equipment Requirements and Standards.

(1) Minimum equipment required. The outpatient setting must have the following equipment and drugs onsite for the handling of emergencies:

(A) monitoring equipment for Level II through Level IV procedures:

(i) pulse oximetry;

(ii) continuous EKG;

(iii) non-invasive blood pressure measured at least every five minutes; and

(iv) if general anesthesia is utilized, an O2 analyzer and end-tidal CO2 analyzer;

(B) appropriate intravenous therapy equipment;

(C) a precordial stethoscope or similar device, and non-electrical blood pressure measuring device, for use in the event of an electrical outage;

(D) emergency equipment appropriate for the purpose of cardiopulmonary resuscitation;

(E) AED or other defibrillator, difficult airway equipment, as well as the drugs and equipment necessary for the treatment of malignant hyperthermia, if using triggering agents associated with malignant hyperthermia or if the patient is at risk for malignant hyperthermia; and

(F) a means to measure temperature, which shall be readily available and utilized for continuous monitoring when indicated per current ASA standards.

(2) Equipment Standards.

(A) Equipment must be appropriately sized for the patient population being served.

(B) All anesthesia-related equipment and monitors must be maintained to current operating room standards.

(C) Regular service or maintenance checks must be completed by appropriately qualified biomedical personnel, at least annually or per manufacturer recommendations.

(D) A separate equipment maintenance log must contain:

(i) service check information including date performed;

(ii) a clear description of any equipment problems and the corrective action; and

(iii) if substandard equipment was utilized without corrective action, a description of how patient safety was protected.

(E) The equipment maintenance log must be retained for seven years from the date of inspection.

(F) An audible signal alarm device capable of detecting disconnection of any component of the breathing system shall be utilized.

(3) Emergency Supplies.

(A) All required emergency supplies must be maintained and inspected by qualified personnel for presence and proper function intervals established by protocol.

(B) All medication, drugs, and supplies must not be expired.

(C) Personnel must be trained on the use of emergency equipment and supplies.

(D) A separate emergency supply log must include dates of inspections. The log must be retained for seven years from the date of inspection.

(4) Emergency Power Supply and Communication Source.

(A) Outpatient settings must have a secondary power source as appropriate for equipment in use, in case of power failure.

(B) A two-way communication source not dependent on electrical current shall be available.

(5) Protocols.

(A) The outpatient setting must have written protocols regarding:

(i) patient selection criteria;

(ii) patients or providers with latex allergy;

(iii) pediatric drug dosage calculations, where applicable;

(iv) ACLS or PALS algorithms;

(v) infection control;

(vi) documentation and tracking use of pharmaceuticals, including controlled substances, expired drugs and wasting of drugs; and

(vii) discharge criteria.

(B) The outpatient setting must have written protocols regarding emergency transfer procedures for cardiopulmonary emergencies that include:

(i) a specific plan for securing a patient's airway pending EMS transfer to the hospital; and

(ii) have appropriate ACLS measures in the office for patient stabilization until EMS arrives.

(C) For outpatient settings that are located in counties lacking 9-1-1 service entities supported by EMS providers licensed at the advanced life support level, physicians must enter into emergency transfer agreements with a local licensed EMS provider or accredited hospital-based EMS. The agreement’s terms must require EMS to bring staff and equipment necessary for advanced airway management equal to or exceeding that which is in place at the outpatient setting.

(D) The written protocols, including the emergency transfer agreements, must be evaluated and reviewed at least annually.

§173.3. Specific Requirements Based on Level of Anesthesia Provided.

In addition to the general standards that apply to all outpatient settings, the following standards are required for outpatient settings, based upon the level of anesthesia being administered. If personnel and equipment meet the requirements of a higher-level, lower-level anesthesia services may also be provided.

(1) Level I Services:

(A) A physician and at least one other personnel must be present during the procedure. Both the physician and the personnel must be currently certified by AHA or ASHI, at a minimum in BLS.

(B) The following age-appropriate equipment must be present:

(i) a bag mask valve; and

(ii) oxygen.

(2) Level II services:

(A) A physician and at least one other personnel must be present during the procedure and recovery until ready for discharge. The physician must be currently certified by AHA or ASHI, at a minimum in ACLS or PALS, as appropriate. The additional personnel member(s) must be currently certified by AHA or ASHI, at a minimum in BLS.

(B) A crash cart must be present containing drugs and equipment necessary to carry out ACLS protocols, including, but not limited to:

(i) the age-appropriate monitoring and emergency equipment required under paragraph (1)(B) of this section;

(ii) pre-measured doses of first line cardiac medications, including epinephrine, atropine, adreno-corticoids, and antihistamines;

(iii) benzodiazepines for intravenous or intramuscular administration;

(iv) lipid emulsion if, administering local anesthesia, peripheral nerve blocks, or both in a total dosage amount that exceeds 50 percent of the recommended maximum safe dosage per outpatient visit (except for Mohs micrographic surgery), or if administering tumescent anesthesia, for treating local anesthetic systemic toxicity; and

(v) specific reversal agents, Flumazenil and Naloxone, if benzodiazepines or narcotics are used for sedation.

(3) Level III services:

(A) A physician and at least one other personnel must be present during the procedure and recovery until ready for discharge. The physician must be currently certified by AHA or ASHI, at a minimum in ACLS or PALS, as appropriate. The additional personnel member(s) must be currently certified by AHA or ASHI, at a minimum in BLS.

(B) A crash cart must be present containing the same drugs and equipment required for Level II, except for lipid emulsion.

(C) A working intravenous feed must be established.

(D) Providers must adhere to ASA Standards for Post Anesthesia Care.

(4) Level IV services: Level IV services do not require physicians to maintain a stock of lipid emulsion. Physicians who provide Level IV anesthesia services in outpatient settings shall follow current, applicable standards and guidelines as put forth by the American Society of Anesthesiologists (ASA) including, but not limited to, the following:

(A) Basic Standards for Preanesthetic Care;

(B) Standards for Basic Anesthetic Monitoring;

(C) Standards for Post Anesthesia Care;

(D) Position on Monitored Anesthesia Care;

(E) The ASA Physical Status Classification System;

(F) Guidelines for Nonoperating Room Anesthetizing Locations;

(G) Guidelines for Ambulatory Anesthesia and Surgery; and

(H) Guidelines for Office-Based Anesthesia.

§173.4. Registration.

Each physician who provides anesthesia services or performs a procedure for which anesthesia services are provided in an outpatient setting, excluding Level I services, shall register with and pay a fee in an amount established by the board.

§173.5. Inspections.

The board may conduct inspections to enforce these rules, including inspections of an operating surgeon's office site or a mobile anesthesia provider's practice and procedures related to storage, transport, and setup of necessary equipment. The board may contract with another state agency or qualified person to conduct these inspections.