

The Texas Medical Board (Board) proposes the repeal of current Chapter 169, concerning Authority of Physicians to Supply Drugs, §§169.1 – 169.8.

The Board also proposes new Chapter 169, concerning Delegation. This includes new Subchapter A, concerning Definitions and General Provisions, §169.1 and §169.2; Subchapter B, concerning Physician Assistants and Advanced Practice Registered Nurses, §169.5; Subchapter C, concerning Emergency Medical Services, §§169.10 – 169.15; Subchapter D, concerning Pharmacists, §169.20; and Subchapter E, concerning Other Delegated Acts, §§169.25 – 169.28.

Also, the Board contemporaneously proposes the repeal of current Chapter 193, concerning Standing Delegation Orders, §§193.1 – 193.13, and current Chapter 197, concerning Emergency Medical Services, §§197.1 – 197.7.

The Board has determined that due to the extensive reorganization of Chapters 160-200, repeal of Chapter 169 is more efficient than proposing multiple amendments to make the required changes.

The proposed new subchapters and section are as follows:

SUBCHAPTER A. DEFINITIONS AND GENERAL PROVISIONS.

New §169.1, Definitions, explains words and terms used in new Chapter 169.

New §169.2, General Responsibilities of Delegating Physician, explains what is required of a physician delegating any medical act.

SUBCHAPTER B. PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE REGISTERED NURSES.

New §169.5, Delegation to a Physician Assistant or Advanced Practice Registered Nurse, explains requirements for a physician delegating medical acts to a physician assistant or an advanced practice registered nurse.

SUBCHAPTER C. EMERGENCY MEDICAL SERVICES.

New §169.10, Definitions, explains the resources for definitions of words and terms used in Subchapter C of new Chapter 169, as applied to physician supervision of emergency medical service (EMS) personnel.

New §169.11, Medical Supervision, explains the statutory authority physicians providing medical control and medical supervision of EMS providers must adhere to.

New §169.12, Medical Director Qualifications, explains the requirements for a physician to be a medical director of EMS services.

New §169.13, Medical Director Responsibilities, explains the responsibilities of a physician acting as medical director of EMS services.

New §169.14, Limits on Off-Line Medical Control, explains the limit on the number of EMS providers an off-line medical director may supervise.

New §169.15, Other Physician Presence at Medical Emergency, explains how care should be provided by another physician, other than an EMS medical director, at the scene of an emergency.

SUBCHAPTER D. PHARMACISTS.

New §169.20, General Standards, explains the general standards expected when a physician delegates to a licensed pharmacist in Texas. Drug therapy management, immunizations, and vaccinations may be authorized by the physician to be performed by the pharmacist under an order, standing medical order, standing delegation order, or protocol.

SUBCHAPTER E. OTHER DELEGATED ACTS.

New §169.25, Other Delegation, explains that delegation is required for non-surgical cosmetic procedures and other medical practices involving administration of other substances for human consumption.

New §169.26, General Standards, explains the responsibilities relating to the delegating physician for other medical procedures.

New §169.27, Physician Responsibilities related to Written Order, explains minimum requirements for orders provided to a non-physician performing delegated acts involving administration of substances for human consumption.

New §169.28, Notice and Identification Provisions, explains notice and identification requirements when performing these other delegated acts.

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 in the 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 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/9LtjjNnzmD>. 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.

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§169.1. Purpose.

§169.2. Definitions.

§169.3. Administration of Drugs.

§169.4. Providing, Dispensing, or Distributing Drugs.

§169.5. Exceptions.

§169.6. Administration or Provision of Drugs in Licensed Facilities.

§169.7. Record Keeping.

§169.8. Policy.

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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. Additionally, the new rules are also proposed in accordance with Texas Occupations Code, Chapter 157 (concerning Authority of Physician to Delegate Certain Medical Acts) and Chapter 158 (concerning Authority of Physician to Provide Certain Drugs and Supplies). The new rules are also proposed in accordance with the requirements of the 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.

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SUBCHAPTER A. DEFINITIONS AND GENERAL PROVISIONS.

§169.1. Definitions.

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

(1) Administer--To directly apply a prescription drug to the body of a patient by any means, including injection, inhalation, or ingestion, by a physician or an individual acting under the delegation and supervision of a physician.

(2) Controlled substance--A substance, including a drug, an adulterant, and a dilutant, listed in and as described under the Texas Health and Safety Code, Chapter 481 (Texas Controlled Substances Act). The term includes the

aggregate weight of any mixture, solution, or other substance containing a controlled substance.

(3) Dangerous drug--A device or a drug that is unsafe for self-medication and that is not included in the Texas Health and Safety Code, Chapter 481 (Texas Controlled Substances Act). The term includes a device or a drug that bears or is required to bear the legend: "Caution: federal law prohibits dispensing without prescription."

(4) Device--means an instrument, apparatus, or contrivance, or a component, part, or accessory of an instrument, apparatus, or contrivance, that is designed or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or that is designed or intended to affect the structure or any function of the body of a human.

(5) Drug therapy management--the performance of patient specific acts by pharmacists as authorized by a physician through a written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician unless the drug product is named in the physician-initiated protocol.

(6) Human consumption--The injection, inhalation, ingestion, or application of a substance to or into a human body.

(7) Medication order--An order from a practitioner or a practitioner's designated agent for administration of a drug or device, as defined by §551.003 of the Occupations Code, or an order from a practitioner to dispense a drug to a patient in a hospital for immediate administration while the patient is in the hospital or for emergency use on the patient's release from the hospital, as defined by Texas Health and Safety Code, §481.002.

(8) Midlevel practitioner--A physician assistant or advanced practice registered nurse.

(9) Nonprescription drug--A nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with state and federal law.

(10) Prescribe or order a drug or device--Prescribing or ordering a drug or device, including the issuing of a prescription drug order or medication order.

(11) Prescription medical device--A device that the federal Food and Drug Administration has designated as a prescription medical device and can be sold only to persons with prescriptive authority in the state in which they reside.

(12) Protocols--Written authorization delegating authority to initiate medical aspects of patient care, including delegation of the act of prescribing or ordering a drug or device at a facility-based practice. Prescriptive authority agreements may reference or include the terms of a protocol(s).

(13) Standing delegation order--Written instructions, orders, rules, or procedures designed for a patient population with specific diseases, disorders, health problems, or sets of symptoms. This type of order provides a general set of conditions and circumstances when action can be instituted prior to being examined or evaluated by a physician. Standing delegation orders may permit the administering or providing of the following types of dangerous drugs if specifically ordered by or using a pre-signed prescription from the delegating physician:

(A) oral contraceptives;

(B) diaphragms and contraceptive creams and jellies;

(C) topical anti-infectives for vaginal use;

(D) oral anti-parasitic drugs for treatment of pinworms;

(E) topical anti-parasitic drugs;

(F) antibiotic drugs for treatment of venereal disease; or

(G) immunizations.

(14) Standing medical orders--Generally applicable orders, which are used as a guide in preparation for and carrying out medical acts or surgical procedures or both after patients have been evaluated by the physician or midlevel provider under delegation.

(15) Written protocol --A physician's order, standing medical order, standing delegation order, or other physician order or protocol.

§169.2. General Responsibilities of Delegating Physician.

(a) When delegating any medical act, a delegating physician must comply with Chapter 157 of the Act. Delegation must be through written protocols or prescriptive authority agreements depending on the type of delegate and the medical acts being delegated.

(b) General standards for Standing Delegation Orders, Standing Medical Orders, and Protocols require:

(1) development and approval by the delegating physician or in accordance with facility bylaws and policies;

(2) the order or protocol to be in writing and signed by the delegating physician;

(3) a description of the specific instructions, orders, protocols, or procedures to be followed,

(4) a notation of the level of supervision required, unless specified by other law;

(5) plans for addressing patient emergencies;

(6) annual review signed by the delegating physician; and

(7) maintenance at the facility or practice site.

(c) These requirements may be different or modified as set out in the specific subchapters below. The specific provisions in a subchapter control over the general standards.

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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. Additionally, the new rules are also proposed in accordance with Texas Occupations Code, Chapter 157 (concerning Authority of Physician to Delegate Certain Medical Acts) and Chapter 158 (concerning Authority of Physician to Provide Certain Drugs and Supplies). The new rules are also proposed in accordance with the requirements of the Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for reoption, reoption with amendments, or repeal every four years. No other statutes, articles or codes are affected by this proposal.

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SUBCHAPTER B. PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE REGISTERED NURSES.

§169.5. Delegation to a Physician Assistant or Advanced Practice Registered Nurse.

(a) When delegating to a physician assistant or an advanced practice registered nurse, a physician must comply with Chapter 157 of the Act.

(b) In accordance with §157.0511(b-2), a delegating physician must register with the board the following information within 30 calendar days of the delegation:

(1) the name and license number of the physician assistant or advanced practice registered nurse;

(2) the beginning date of the delegation; and

(3) the location(s) where the delegate(s) practice.

(c) The delegating physician must notify the board in writing of the termination of delegation authority within 30 calendar days of termination. Any party to the agreement may submit the notice of termination.

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SUBCHAPTER C. EMERGENCY MEDICAL SERVICES.

§169.10. Definitions.

The definitions found in the Health and Safety Code, Chapter 773, and Title 25, Texas Administrative Code, Chapter 157, including medical control, medical direction, medical oversight, medical supervision, and off-line medical direction, apply to physician supervision of emergency medical service (EMS) personnel under this subchapter.

§169.11. Medical Supervision.

Physicians providing medical control and medical supervision of emergency medical service (EMS) providers are subject to Chapter 157 of the Act and the board rules related to physician supervision and delegation.

§169.12. Medical Director Qualifications.

(a) In addition to holding an active Texas medical license, a medical director must meet all applicable standards as set forth in Title 25, Texas Administrative Code, Chapter 157 (related to Emergency Medical Care) for the emergency medical service (EMS) services being provided, training, education, and other delineated responsibilities.

(b) A medical director must complete one of the following requirements:

(1) a minimum of 12 hours of formal continuing medical education (CME), in the area of EMS medical direction within two years of initial notification to the Board of becoming a medical director;

(2) board certification in Emergency Medical Services by either the American Board of Medical Specialties or American Osteopathic Association; or

(3) a Texas Department of State Health Services (DSHS) approved EMS medical director course.

(c) A medical director must complete one hour of formal CME in the area of EMS medical direction in each subsequent biennial renewal of the registration.

§169.13. Medical Director Responsibilities.

A Medical Director must:

(1) register with the board on an approved form and provide all required documentation requested;

(2) review, approve, and sign protocols and/or standing delegation orders of emergency medical service (EMS) providers regarding:

(A) prehospital care, to be provided by EMS personnel;

(B) patient transport standards (voluntary and involuntary);

(C) criteria for selection of a patient's destination; and

(D) standard of care to be provided, patient care incidents, patient complaints, and deviations from established protocols.

(3) assist in developing, implementing, and revising protocols and/or standing delegation orders, as appropriate; and

(4) monitor compliance with protocols and standing orders by EMS providers.

§169.14. Limits on Off-Line Medical Control.

(a) If the medical control is provided as an off-line medical director, the medical director may not supervise more than 20 emergency medical service (EMS) providers unless a written request for a waiver is submitted to the board on the board approved form.

(b) Once received, the board will forward the waiver request to the Texas Department of State Health Services (DSHS). If approved, the board will update the registration as appropriate.

§169.15. Other Physician Presence at Medical Emergency.

(a) In the event a physician who is not the medical director is present at the scene of an emergency, the care provided by that physician must be appropriate for the circumstances.

(b) The medical director and physician present must communicate and coordinate care as appropriate under the circumstances.

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SUBCHAPTER D. PHARMACISTS.

§169.20. General Standards.

(a) In accordance with §157.001 and §157.101 of the Act, a physician licensed to practice medicine in Texas may delegate to a properly qualified and trained pharmacist acting under adequate supervision the performance of specific acts of drug therapy management, immunizations and vaccinations authorized by the physician through the physician's order, standing medical order, standing delegation order, other order, or protocol.

(b) A written protocol or order for drug therapy management must contain at a minimum:

(1) the identity of the physician and the pharmacist engaging in drug therapy management;

(2) the condition requiring drug therapy;

(3) the drugs to be used drug therapy management authorized, including allowing generically equivalent drug selection unless otherwise indicated; and

(4) the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority, including maintaining a record for each patient.

(c) A written protocol or order for immunizations and vaccination must contain at a minimum:

(1) the location(s) at which the pharmacist may administer immunizations or vaccinations;

(2) the immunizations or vaccinations that may be administered;

(3) procedures to follow when administering immunizations or vaccinations including:

(A) a requirement that if the patient is under 14 years of age, they have a physician referral;

(B) procedures if adverse reactions occur; and

(C) a requirement to report to the delegating physician the administration of the immunization or vaccination within 24 hours after administration.

(D) A periodic review and update, if necessary, of a written protocol for drug therapy management, immunizations, and vaccinations are required.

(E) A physician who provides care to persons over 65 years of age must comply with Chapter 161.0052 of the Texas Health and Safety Code regarding pneumococcal and influenza vaccines.

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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. Additionally, the new rules are also proposed in accordance with Texas Occupations Code, Chapter 157 (concerning Authority of Physician to Delegate Certain Medical Acts) and Chapter 158 (concerning Authority of Physician to Provide Certain Drugs and Supplies). The new rules are also proposed in accordance with the requirements of the 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.

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SUBCHAPTER E. OTHER DELEGATED ACTS.

§169.25. Other Delegation.

(a) In accordance with §157.001 of the Act, the board determined the following to be the practice of medicine and such medical acts can be properly delegated and supervised:

(1) nonsurgical medical cosmetic procedures, including but not limited to the injection of medication or substances for cosmetic purposes, the administration of colonic irrigations, and the use of a prescription medical device for cosmetic purposes; and

(2) using a device to administer for human consumption a nonprescription drug, dangerous drug, or controlled substance.

(b) This does not include those delegations specifically authorized and described in Chapter 157 of Act or to procedures performed at a physician's practice by the physician or midlevel practitioners acting under the physician's supervision.

§169.26. General Standards.

(a) The delegating physician must ensure the individual performing these medical acts:

(1) has appropriate training regarding:

(A) techniques for the delegated act including pre-procedural care, post-procedural care, and infectious disease control;

(B) contraindications for the delegated act; and

(C) recognition and acute management of potential complications; and

(2) signs and dates a written protocol.

(b) A physician must either be appropriately trained or be familiar with and able to perform the delegated medical act according to the standard of care;

(c) Prior to performance of the delegated act, a physician, or a midlevel practitioner acting under the delegation of a physician, must:

(1) establish a practitioner-patient relationship;

(2) complete and maintain an adequate medical record in accordance with Chapter 163 of this title;

(3) disclose the identity and title of the individual who will perform the delegated act; and

(4) ensure at least one person trained in basic life support is present while the patient is onsite.

(d) A physician or midlevel practitioner must either:

(1) be onsite during the procedure; or

(2) be immediately available for emergency consultation in the event of an adverse outcome; and

(3) if necessary, the physician must be able to conduct an emergency appointment with the patient.

§169.27. Physician Responsibilities Related to Written Order.

(a) A physician may delegate acts under this subsection only if the physician has either:

- (1) reviewed and approved in writing the business' or facility's existing written order; or
- (2) developed their own written orders for the delegated acts.

(b) The written order must include:

- (1) the identity of the delegating physician responsible for the delegation of the procedure;
- (2) selection criteria for screening patients;
- (3) a description of appropriate care; and
- (4) procedures for common complications, serious injuries, or emergencies, including communication or feedback to the delegating physician or midlevel practitioner.

§169.28. Notice and Identification Provisions.

(a) Any individual, business, or facility providing any of the delegated acts under this subsection must post the following in each public area and treatment room:

- (1) the notice of how to file a complaint with the board required under §177.2 of this title (relating to Mandatory Complaint Notification); and
- (2) the name(s) of the delegating physician(s) including their Texas medical license number.

(b) Each person performing a delegated act under this subsection must be readily identified by a name tag or similar means that clearly delineates the identity and credentials of the person.