TITLE 22. EXAMINING BOARDS

PART 9. TEXAS MEDICAL BOARD

CHAPTER 193. STANDING DELEGATION ORDERS

The Texas Medical Board (Board) adopts the repeal of §§193.1 - 193.10 and 193.12 and new §§193.1 - 193.20, concerning Standing Delegation Orders. The repeal of §§193.1 - 193.10 and 193.12 and new §§193.3 - 193.7, 193.9, 193.11, 193.12 and 193.14 - 193.20 are adopted without changes to the proposed text as published in the September 13, 2013, issue of the *Texas Register* (38 TexReg 5985) and will not be republished. New §§193.1, 193.2, 193.8, 193.10 and 193.13 are adopted with changes to the proposed text as published in the September 13, 2013, issue of the *Texas Register.* The text of the rules will be republished.

BACKGROUND AND SUMMARY OF THE FACTUAL BASIS FOR THE REPEAL

The current sections are repealed because new §§193.1 - 193.20 are adopted contemporaneously in this issue of the *Texas Register.* The Board has determined that due to the extensive reorganization of Chapter 193, repeal of the entire chapter and replacement with new sections is more efficient than proposing multiple amendments to make the required changes. The new sections of Chapter 193 are adopted to make Chapter 193 consistent with changes made to the Texas Occupations Code Annotated Chapter 157, Subchapter B, concerning delegation to advanced practice registered nurses and physician assistants, by Senate Bill 406, 83rd Legislature, Regular Session (2013). The Board is mandated under the terms of Senate Bill 406 to adopt rules implementing the changes in the Occupations Code Chapter 157. The Board's purpose in adopting the new provisions in Chapter 193 is to encourage the more effective utilization of the skills of physicians by establishing guidelines for the delegation of health care tasks to qualified non-physicians providing services under reasonable physician control and supervision where such delegation and supervision is consistent with the patient's health and welfare; and to provide guidelines for physicians so that existing legal constraints should not be an unnecessary hindrance to the more effective provision of health care services.

SECTION-BY-SECTION SUMMARY

New §193.1, concerning Purpose, describes the intended purpose of Chapter 193 and sets forth its statutory basis.

New §193.2, concerning Definitions, provides definitions for important terms and phrases used in Chapter 193. New terms and phrases defined include: prescriptive authority agreement, device, facility-based practice site, health professional shortage areas (HSPA), hospital, medication order, nonprescription drug, physician group practice, practice serving a medically underserved area, prescribe or order a drug or device, and prescription drug.

New §193.3, concerning Exclusion from the Provisions of this Chapter, sets forth certain limited exclusions to the operation of the Chapter 193.

New §193.4, concerning Scope of Standing Delegation Orders, describes the scope of standing delegation orders and incorporates new terms and definitions consistent with the changes to Chapter 157 of the Occupations Code.

New §193.5, concerning Physician Liability for Delegated Acts and Enforcement, sets forth the applicable limitation on the liability of physicians based solely on signing a prescriptive authority agreement or delegation order. This section further states that delegating physicians remain responsible to the Board and their patients for acts performed under the physicians' delegated authority.

New §193.6, concerning Delegation of Prescribing and Ordering Drugs and Devices, sets forth the general

requirements and limitations related to the delegation and prescribing and ordering of drugs or devices. This section prohibits the delegation of the prescriptive authority for Schedule II drugs, except in facility-based practices under §157.054 of the Occupations Code. Prescribing under prescriptive authority agreements eliminates former requirements for site-based supervision.

New §193.7, concerning Prescriptive Authority Agreements Generally, provides that physicians may delegate to advanced practice registered nurses and physician assistants the act of prescribing or ordering a drug or device through a prescriptive authority agreement and limits the combined number of advanced practice registered nurses and physician assistants with whom a physician may enter into a prescriptive authority agreement to seven. The section sets forth an exclusion to the limit of seven prescriptive authority agreements when exercised in facility-based practices in hospitals or long-term care facilities, subject to certain limitations, and in practices serving medically underserved populations. Prescribing under prescriptive authority agreements pursuant to this section eliminates former requirements for site-based supervision.

New §193.8, concerning Prescriptive Authority Agreements: Minimum Requirements, sets forth minimum requirements for valid prescriptive authority agreements, including requirements for periodic face-to-face meetings with the supervising physicians to discuss patient care and improvement of patient care.

New §193.9, concerning Delegation of Prescriptive Authority at Facility-Based Practice Sites, describes the requirements for delegating the prescribing or ordering of a drug or device at a facility-based practice site. This section states that the limitations on the number of advanced practice registered nurses and physician assistants delegated to under prescriptive authority agreements do not apply to a physician whose practice is facility-based under Chapter 193, subject to certain limitations. This section also addresses requirements for physician supervision and states that the constant physical presence of a physician is not required. This section also addresses requirements for physician supervision and states that the constant physical presence of a physician is not required.

New §193.10, concerning Registration of Delegation and Prescriptive Authority Agreements, describes the requirements for physicians to register information with the Board regarding prescriptive authority agreements entered into with advanced practice registered nurses and physician assistants. This section also states that the Board shall maintain and exchange information with the Texas Board of Nursing and Physician Assistant Board as well as creating and making available to the public an online list of physicians, advanced practice registered nurses, and physician assistants who have entered into prescriptive authority agreements.

New §193.11, concerning Prescription Forms, provides that prescription forms shall comply with applicable rules adopted by the Texas Board of Pharmacy.

New §193.12, concerning Prescriptive Authority Agreements, provides the Board authority to enter, with reasonable notice, a site where a party to a prescriptive authority agreement is practicing, to inspect and audit records or activities related to the implementation and operation of the agreement.

New §193.13, concerning Delegation to Certified Registered Nurse Anesthetists, authorizes the delegation of the ordering of drugs and devices to a certified nurse anesthetist in a licensed hospital or ambulatory surgical center, for the purpose of the nurse anesthetist administering an anesthetic or anesthesia-related service ordered by a physician.

New §193.14, concerning Delegation Related to Obstetrical Services, describes the authority, requirements, and limitations, related to delegating to physician assistants offering obstetrical services and advanced practice registered nurses recognized by the Texas Board of Nursing as nurse midwifes, the act or acts of administering controlled substances related to intra-partum and post-partum care.

New §193.15, concerning Delegated Drug Therapy Management, describes the authorization for, requirements, and limitations related to the delegation by physicians to pharmacists of drug therapy management.

New §193.16, concerning Delegated Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol, describes the authorization for, requirements, and limitations related to the delegation of the administration of immunizations and vaccinations to a pharmacist.

New §193.17, concerning Nonsurgical Medical Cosmetic Procedures, describes the duties and responsibilities of a physician who performs or who delegates the performance of a nonsurgical medical cosmetic procedure.

New §193.18, concerning Pronouncement of Death, authorizes physicians to receive information from Texas licensed vocational nurses through electronic communication for the purposes of making a pronouncement of death.

New §193.19, concerning Collaborative Management of Glaucoma, sets forth the minimum standards for the collaborative treatment of glaucoma.

New §193.20, concerning Immunization of Persons Over 65 by Physicians' Offices, sets forth requirements that physicians providing ongoing primary or principal care to persons over 65 (elderly persons) offer, to the extent possible, pneumococcal and influenza vaccines to each elderly person receiving care at the office.

Comments:

The Board received comments on the proposed rules from the Texas Medical Association (TMA) and the Texas Academy of Family Physicians (TAFP) (submitted jointly), the Texas Society of Anesthesiologists (TSA), the Texas Academy of Physician Assistants (TAPA), the Texas Nurses Association (TNA), the Coalition for Nurses in Advanced Practice (CNAP), the Texas Association of Community Health Centers (TACH), the Texas Association of Nurse Anesthetists (TANA), the Texas Association of Aesthetic Nurses (TAAN), and approximately 106 individuals, including an Austin-based health law attorney.

Section 193.1. Purpose

Commenter: TMA and TAFP (submitted jointly)

The Board received comments regarding §193.1 submitted jointly by TMA and the TAFP.

1. TMA and TAFP do not oppose the changes made to §193.1, which they characterize as "minor".

2. TMA and TAFP support the purpose for Chapter 193 as set forth in the proposed rule and state "the purpose is clear, and underscores the fact that delegation must be made under reasonable physician control and supervision, and must be consistent with the patient's health and welfare."

Section 193.2. Definitions

Commenter: TMA and TAFP (submitted jointly)

TMA and TAFP support all definitions as written.

Section 193.2(2)

Commenter: CNAP

1. Under §193.2(2), the definition of "authorizing physician" does not include a physician's or physicians' use of protocols as a mechanism for delegating prescriptive authority as allowed in §193.9(c)(1). CNAP proposed the following language: "(2) Authorizing physician--A physician or physicians licensed by the board who execute a standing delegation order, protocol or prescriptive authority agreement."

2. CNAP comments that the Board does not use the term authorizing physician consistently throughout the proposed rules, and that it would be more consistent if the term "delegating physician" was changed to "authorizing physician" in §§193.5(b), 193.6(b)(3) and (4), and 193.11.

Response to Comments on §193.2(2)

The use of protocols as an authorized delegating mechanism for physicians is clearly and unequivocally authorized by the terms of §193.9(c)(1), which do not use the term "authorizing physician." Therefore, the Board believes that it is not necessary to add the term "protocols" to the definition §193.2(2). The Board's use of the term "delegating physician" was consistent with the terms use in SB 406. Accordingly, the Board declines to amend the language of §§193.2(2), 193.5(b), 193.6(b)(3) and (4), and 193.11.

Section 193.2(6)

Commenter: CNAP

CNAP comments that the proposed §193.2(6) be amended to refer to the Texas Medical Practice Act rather than "the Act."

Response to Comments on §193.2(6)

The Board agrees with CNAP's comments and has defined the Texas Medical Practice Act as "the Act" at the beginning of Chapter 193 to address this issue, specifically in §193.1. Accordingly, the reference to "the Act" in §193.2(6) will be left in place. The definition of the Texas Medical Practice Act as "the Act" in §193.2(17) has been deleted and replaced with "the Act."

Section 193.2(8)

Commenter: Individual

An Austin-based health law attorney comments that the definition of "hospital" in §193.2(8) is confusing because it references numerous definitions contained in other statutes. This attorney suggests that all of the definitions be set out and included in the definition for facility based practice site at §193.2(6).

Response to Comments on §193.2(8)

The language in the §193.2(8) accurately tracks the language in SB 406 and clearly implements the legislature's intent. The Board declines to amend the language in §193.2(8)

Section 193.2(12)

Commenter: TNA

1. The references in proposed rule §193.2(12) to "§162.1(b) of this title" and "Chapter 162 of this title" are incorrect references to sections of Board rules in the Texas Administrative Code. Chapter 162 of the Board rules relates to the supervision of medical students and not to physician group practices. The definition of "physician group practice" in SB 406 does reference Chapter 162, but it is a reference to Chapter 162 of the Texas Occupations Code, not the Administrative Code. It also refers to §162.001(b) and not §162.1 as the proposed rule.

2. The references in proposed Rule §193.2(12) need to be changed so that they also refer to the Occupations Code. TNA believes the incorrect references are likely a clerical error.

Commenter: CNAP and TACH (presented separately)

Both CNAP and TACH point out that the citation in §193.2(12) to §162.01 of the Act is incorrect and should instead cite to §162.001(b) of the Medical Practice Act.

Response to Comments on §193.2(12)

The Board agrees with the comments from the TNA, CNAP, and TACH that the definition of "Physician Group Practice" in proposed rule §193.2(12) contains an incorrect reference to the Medical Practice Act. The current language of §193.2(12) references "§162.1(b) of this title (relating to Supervision of Medical Students) that complies with the requirements of Chapter 162 of this title." The correct reference in the definition, which accurately reflects the language in SB 406, should read "§162.001(b) of the Act (relating to Regulation by Board of Certain Nonprofit Health Corporations), that complies with the requirements of Chapter 162 of the Act."

Accordingly, the Board modified and adopted the following nonsubstantive language at its October 18, 2013 meeting:

(12) Physician group practice--An entity through which two or more physicians deliver health care to the public through the practice of medicine on a regular basis and that is:

(A) owned and operated by two or more physicians; or

(B) a freestanding clinic, center, or office of a nonprofit health organization certified by the board under §162.001(b) of the Act (relating to Regulation by Board of Certain Nonprofit Health Corporations), that complies with the requirements of Chapter 162 of the Act.

Section 193.2(17)

Commenter: TNA

1. TNA suggests that proposed rule §193.2(17) be modified with the following language: "with the exception of: (a) a facility-based practice pursuant to §157.054 of the Medical Practice Act ("the Act"), Texas Occupations Code Annotated, §§157.051 - 157.060 and this title; or (b) the delegation of ordering of drugs and devices necessary for a nurse anesthetist to administer an anesthetic or an anesthesia-related service pursuant to §157.058 of the Act."

2. The rationale for the above changes is that §157.058 is a separate source of authority for physicians to delegate to CRNAs the ordering of drugs and devices necessary for a CRNA to administer anesthetics or anesthesia-related services. The delegation under §157.058 may be through delegation mechanisms other than prescriptive authority agreements (PAAs) under §157.0512 or protocols under §157.054.

3. TNA additionally suggests moving the portion of §193.2(17) beginning with the phrase "prescriptive authority agreements are required for," including the new subsections (a) and (b) described above, to a new location, specifically, the beginning of §193.7, Prescriptive Authority Agreements Generally.

4. The rationale for moving this section is that this language relating to when a PAA must be used is a substantive provision which TNA believes would be better placed in the substantive sections of the rules rather than included as part of a definition.

Commenter: CNAP

1. CNAP comments that the definition of prescriptive authority agreement §193.2(17) makes it clear that a PAA

is not required in a facility-based practice, but does not acknowledge that §157.058 of the Medical Practice Act provides CRNAs authority to prescribe without prescriptive authority agreements.

2. CNAP recommends changing the definition of §193.17 to add a subsection (a) referencing prescribing in a facility based practice, and a subsection (b) referring to delegation pursuant to §157.058 of the Act.

3. The suggested language by the CNAP is essentially the same as the suggested language by the TNA, described above.

4. CNAP comments that the language in subsections (a) and (b) be added to §193.7 for clarity.

Commenter: TANA

1. TANA's recommendations for modifying the language of §193.2(17) and moving the modified portions to §193.7 are essentially identical to the suggestion submitted by the TNA and CNAP.

2. The rationale for the change is that §157.058 is a separate source of authority for physicians to delegate to CRNA the ordering of drugs and devices that is separate from delegating through prescriptive authority agreements (pursuant to §157.0512 of the Act) or through protocols (pursuant to §157.054).

3. The rationale for moving the language is that the language relating to the PAA would be better placed in a substantive section of the rules.

Response to Comments on §193.2(17)

The Board notes that the comments submitted by the TMA and the TAFP supported the definition as written, and in particular voiced support for the inclusion of language stating that PAAs are required for the delegation of prescriptive authority in all practice settings with the exception of facility based practices. This language was inserted by the Board to clarify the role of PAAs under SB 406.

The Board agrees with the TNA and the CNAP that PAAs are not required for the delegation and ordering of drugs and devices necessary for a nurse anesthetist to administer or perform anesthesia-related service pursuant to §157.058 of the Act. However, the Board does not believe that adding language to this effect to the §193.2 (17) definition is necessary as the language of §157.058 is clear and stands on its own. The Board also views the language clarifying the scope of prescriptive authority agreements as definitional, rather than substantive, and believes that this language should remain in its present location, rather than be removed to the beginning §193.7. Accordingly the Board declines to amend the rule as suggested.

Section 193.5. Physician Liability for Delegated Acts and Enforcement

Commenter: TMA and TAFP (submitted jointly)

1. The TMA and TAFP strongly support the need for a statement regarding a physician's potential liability with regards to the delegation and supervision of prescriptive authority.

2. TMA and TAFP comment that the proposed language stating that a delegating physician remains "responsible" to the Board and to their patient for acts performed under the physician's act implies ultimate liability for the delegated act, while the issue of liability will actually depend on circumstances.

3. The language in the statute and rule, stating that a physician is not liable for the acts of a PA or APN *solely* on the basis of having signed a delegation order, has caused confusion to physicians when they found themselves liable to the TMB for the acts of PAs and APRNs to whom they have delegated. The addition of language regarding a physician's ultimate liability will help highlight to physicians the gravity of delegating

medical acts to mid-level practitioners and the importance of appropriate supervision.

4. The TMA and TAFP are concerned that the language "remains responsible to their patients" might be used in civil litigation or by a court to establish vicarious liability.

5. The issue of whether a physician is liable to the Board for an inappropriate delegation or supervision depends on the circumstances of the delegation or supervision. For example, if a physician delegates acts that are not commensurate with the APRN's or PA's training, education, or experience, and does not appropriately supervise or continues to allow a delegation despite a history of substandard care, then that physician may be liable for a bad act performed by an APRN or PA. However, if a physician delegates to an APRN or PA with a high level of experience, education and training in a certain field, an act consistent with that experience and supervises appropriately, then that physician may not be found liable by the TMB for a negligent act the APRN or PA performs despite the physician's proper supervision.

6. The proposed rule does not make the above distinction clear and leads to confusion and potential misinterpretation.

7. The TMA and TAFP recommend modifying the proposed language of §193.5(b) to read "Notwithstanding subsection (a) of this section, the delegating physicians remain liable for acts performed under the physicians delegated authority if the delegation was not performed in accordance with the standard of care."

8. The rule should not imply that APRNs or PAs are absolved from their own liability and should add a statement that APRNs and PAs remain professionally responsible for acts performed under the scope and authority of their own licenses.

Commenter: TNA

1. TNA recommend amending proposed rule §193.5(b) to read "Notwithstanding subsection (a) of this section, delegating physicians remain responsible to the Board and to their patients for the proper delegation and supervision of acts performed under the physician's delegated authority."

2. TNA is aware that subsection (b) is taken from current TMB Rule §193.6(a). However, TNA believes that the proposed language more accurately reflects what the physician is accountable for and also makes subsections (a) and (b) read more consistently. TNA believes the intent of §157.058 (which subsection (a) tracks) is that a physician should not be liable for the acts of an APRN/PA which the physician has appropriately delegated and supervised. TNA also believes the change is consistent with the discussion of this issue at TMB's August 30th Board meeting.

Commenter: CNAP

1. The CNAP comments that §193.5 could be clarified by amending subsection (b) to more accurately reflect what a physician is accountable for when delegating prescriptive authority. CNAP further recommends "language that currently exists in §193.6, but is being proposed for repeal, be included in these new rules, so APRNs and PAs are clear on their responsibilities."

2. The CNAP recommends amending §193.5(b) as follows: "(b) Notwithstanding subsection (a) of this section, delegating authorizing physicians remain responsible to the Board and to their patients for the proper delegation and supervision of acts performed under the physician's delegated authority; (d) Advanced practice registered nurses and physician assistants remain professionally responsible for acts performed under the scope and authority of their own licenses."

Response to Comments on §193.5

TMA, TAFP, and TNA comments state that there has been confusion regarding physicians' violation of the Act and Board Rules relating to delegation and supervision, and particularly delegation of prescriptive authority. In addressing these concerns, the Board has grouped together provisions related to liability for delegation and supervision into §193.5. These provisions were formerly located at §§193.6(m), 193.6(a), and 193.5.

The Board disagrees that the language in subsection (b) stating that the delegating physician remains responsible to the Board and to their patients for acts performed under the physician's care implies liability for any delegated act. Subsection (a) makes clear that a physician will be liable for improper delegation based solely on signing a delegation order only if the physician had reason to believe that the physician assistant or advanced practice registered nurse lacked competency to perform the delegated acts, at the time the delegation order was signed. Rather, the Board has consistently interpreted the language in subsection (b) (formerly §193.6 (a)) as requiring a fact-based inquiry into the specific circumstances of the delegation and supervision by a physician before holding a physician liable for a delegated act by a PA or APRN.

TMA submitted comments concerning the possible use of the language §193.5(b) to establish vicarious liability for a physician in a civil proceeding. Also related to this comment, the TMA submitted suggested language amending §193.5(b). The Board disagrees with the TMA's use of term "standard of care" in their suggested amendment. An analysis of whether a violation occurred is not necessarily based solely on the violation of standard of care by a PA or APRN and may include other issues related to the appropriateness of supervision and acts delegated.

The language suggested by TNA that a "delegating physicians remain responsible to the Board and to their patients for the proper delegation and supervision of acts performed under the physician's delegated authority" is confusing. Physicians are subject to potential disciplinary action by the Board, based on improper delegation and supervision of acts performed under their delegated authority, rather than for proper delegation and supervision.

The Board also disagrees that new language should be added to §193.5 emphasizing that PAs and APRNs remain liable for their acts under delegation under the scope and authority of their own licenses. This language is unnecessary as the licensing and disciplinary statutes and rule governing APRNs and PAs already addresses this issue.

Accordingly, the Board declines to amend the language of §193.5.

Section 193.6. Delegation of Prescribing and Ordering Drugs and Devices

Commenters: TMA and TAFP (submitted jointly)

1. The TMA and TAFP support the proposed changes, and particularly support the addition, in subsection (c), of the term "hospital" to facility based practice, as it was the intent of SB 406 to limit the delegation of Schedule II substances to hospitals and not to facility based practices in general.

2. The legislative intent to limit delegation of Schedule II substances to hospitals is supported by the addition of the definition of "hospital" to Texas Occupations Code, §157.051. This definition defines a hospital narrowly under §241.003 and Chapter 557 of the Texas Health and Safety Code.

3. It is imperative that the limitation on delegation of Schedule II drug to "hospitals" be emphasized. TMA and TAFP recommend adding clarifying language to subsection (c) to explicitly exclude outpatient clinics affiliated with hospitals from Schedule II delegation.

Commenter: TAPA

1. TAPA recommends modifications to §193.6(b)(2) and (3) to address patient safety care issues. TAPA

acknowledges these modification are not related to SB 406.

2. The current language of §193.6(b)(2) and (3) suggests only one refill may be prescribed by a PA under delegated prescriptive authority.

3. A single refill causes patient care and safety issues because it encourages 60 day refills.

4. For the treatment of certain patients and conditions, for example pain management, a single 60 day refill may exacerbate the habit inducing effect of certain drugs prescribed in pain management care to the detriment of the patient's safety and wellbeing.

5. TAPA recommends the language of §193.6(b)(2) be modified to read "the prescription including refills of the prescription is not to exceed 90 days".

6. TAPA recommends the language of §193.6(b)(3) be modified to read "with regard to refills of a prescription, the refill is authorized after consultation with the delegating physician and the consultation is noted in the patient's chart; and".

7. The suggested language would ensure that the needs of the patient's care and safety are the only factors being considered when a PA is prescribing a refill, while also staying within the intent of the statute.

Response to Comments on §193.6

The Board agrees with the TMA that the intent of SB 406 delegation of Schedule II drugs is limited to hospital facility based practices and inserted appropriate language to reflect that intent. The Board believes that the language set out in §193.6(c)(1) and (2) makes this limitation clear and that an additional provision specifically excluding outpatient clinics of hospitals from Schedule II delegation is not necessary. The Board additionally notes that the legislature did not include such an exclusion in SB 406. The Board declines to add TMA's suggested language related to outpatient clinics.

TAPA acknowledges that the requested modification of the language of §193.6(b)(2) is not required by the terms of SB 406. The language in the Occupations Code related to refills is unchanged and is reflected by the language of the current proposed Board rule. The Board disagrees that there is a need to change the language, and points out that the legislature had an opportunity to address this issue in SB 406 and chose not to take any action.

Section 193.7. Prescriptive Authority Agreements Generally

Commenters: TMA and TAFP

TMA and TAFP support the proposed rules as written.

Commenter: TNA

1. TNA requests modifying the language of proposed rule §193.7(e)(2) as follows: "(2) a facility-based practice in a hospital under §157.054, subject to the limitations in §157.054(a-1) of the Act and §193.9(c)(4) of this title (relating to Delegation of Prescriptive Authority at a Facility-Based Practice Site)."

2. It is not clear why proposed Rule §193.7(e) references §157.054(b-1) and §193.9(b)(5) on the one hand, and, on the other, proposed Rule §193.9(b) references §193.9(b)(4). Section 157.054(b-1) and §193.9(b)(5) address the number of facilities (one hospital; two LTC facilities) at which a facility-based physician may delegate. Section 193.9(b)(4), on the other hand, addresses the number of FTEs (seven) to whom a physician may delegate in a LTC facility-based practice. TNA believes the appropriate reference in both rules is §157.054(a-1)

(relating to FTE limits in facility based practices) and §193.9(c)(4) (relating to FTE limit in LTC).

Response to Comments on §193.7

The Board staff disagrees with the TNA's comments related to §193.7(e). The Rule as drafted is consistent with SB 406 related to the limitations on facility based prescribing and implements the intent of the legislature. The Board declines to amend §193.7(e).

193.8. Prescriptive Authority Agreements: Minimum Requirements

Commenters: TMA and TAFP

The TMA and TAFP support the proposed rules as written.

Commenter: TAPA

1. The language in proposed §193.8(10)(C) is not compatible with SB 406 and the express language of §157.0512(f)(2)(B).

2. The express language of §157.0512(f)(2)(B) does not require that a PA be in the same practice with the same physician in which the PA will be entering into a prescriptive authority agreement.

3. The express language of the statute is to recognize the experience gained by a PA who has been in a practice that included the exercise of prescriptive authority, and "to allow for the face-to-face meeting be conducted monthly for the first year only, rather than 3 years without the five year experience, and move to quarterly face-to-face meetings."

4. Section 193.8(10)(C) does not reflect the express language or intent of SB 406 because it requires the PA's five year experience to be with the physician with whom the PA will be entering into a prescriptive authority agreement.

5. TAPA suggests removing the proposed language of §193.8(10)(C) and replacing it with the language of §157.0512(f)(2)(B) verbatim.

Commenter: TNA

1. TNA submitted comments regarding §193.8(10)(C).

2. TNA requests the deletion of the qualifier "with whom the prescriptive authority agreement is entered," for three reasons.

3. First, adding the qualifier is contrary to the intent of the Legislature in enacting §157.0512(f)(2)(B), and the statutory scheme reflected in SB 406 when §157.0512(f)(2)(B) is read in combination with Section 28 of SB 406.

4. Section 157.0512(f)(2)(B) and Section 28 address two different types of experience. Section 28 addresses specific experience in exercising prescriptive authority under the supervision of the physician signing the PAA, while §157.0512(f)(2)(B) addresses general experience in exercising prescriptive authority under the required supervision of a physician other than the physician signing the PAA.

5. Adding the qualifier, as done in the proposed rule, eliminates any recognition of an APRN's/PA's prior general experience of exercising prescriptive authority under the required supervision of a physician other than the physician signing the PAA.

6. Second, adding the qualifier makes (C) meaningless because Section 28 of SB 406 requires that time spent prior to 11/1/13 under the delegated prescriptive authority of the physician signing the PAA be included when calculating how long the PAA has been in effect. Any APN who has prescribed for five out of the last seven years under the delegated authority of the physician signing the PAA will automatically qualify under §193.8 (10)(B)(ii) to begin quarterly meetings.

7. Third, adding the qualifier violates the prohibition in §157.0512(p) that TMB not adopt rules that "would impose requirements in addition to the requirements under this section."

8. TNA requests that the word "supervised" in §193.8(10)(C) be deleted in the phrase "was supervised for." The use of "supervised" in that phrase seems redundant with "required supervision" later in the sentence and deleting "supervised" in the phrase "was supervised for" makes the sentence easier to read. TNA does not believe this a substantive change.

Commenter: CNAP

The CNAP comments that the phrase "by the physician with whom the prescriptive authority agreement is entered" is not included in SB 406 and improperly adds an additional requirement to the elements of a prescriptive authority agreement. CNAP recommends removal of the phrase.

Commenter: TACH

TACH requests that the phrase "by the physician with whom the prescriptive authority agreement is entered," in §193.8(10)(C), be removed because it is contrary to the intent of SB 406 which references the experience of an APRN or PA for at least five years in a practice that included the exercise of prescriptive authority with required physician supervision. TACH adds that SB 406 does not limit that experience to experience with one physician.

Response to Comments on §193.8

After reviewing submitted comments and the language of SB 406, the Board has determined that SB 406 contemplates various standards for periodic face-to-face meetings based on the experience of the parties with delegated prescriptive authority under physician supervision. SB 406 acknowledges that some physician assistants and advanced practice registered nurses have greater experience in practices involving delegated prescriptive authority under physician supervision, and therefore require less frequent face-to-face meetings to ensure patient safety and quality of care. Board staff declines to modify the language of §193.8 dealing with the frequency of periodic face-to-face meetings as suggested by various commenters, but has incorporated portions of the comments as described below. In order to clarify the various levels of experience which determine the frequency of periodic face-to-face meetings, Board staff has revised the rules to require three different standards for periodic face-to-face meetings, based on the parties experience with delegated prescriptive authority under physician supervision. These standards are consistent with the language of SB 406 and implement its intent. These standards reflect that the length of experience with delegated prescriptive authority under physician supervision, combined with a longer relationship between the parties, allows for less intensive monitoring by the delegating physician. The first standard addresses a lower level of experience with delegated prescriptive authority under physician supervision. The second level recognizes parties that have experience with delegated prescriptive authority under physician supervision but are entering into prescriptive authority agreements with new parties, or a physician who has not supervised them for five full years. The section of the rule dealing with the second standard incorporates comments requesting that the qualifying language "with whom the prescriptive authority agreement is being entered" be removed from language related to physician assistants and advanced practice registered nurses with five years of experience in a practice with delegated authority under physician supervision. The third standard recognizes parties with five full years of experience in delegated prescriptive authority under the same supervising physician, who are continuing that pre-existing relationship under a prescriptive authority agreement.

Section 193.10

Commenters: TMA and TAFP

1. The majority of the proposed section is consistent with SB 406.

2. Even though SB 406 is silent as to a requirement for a physician to notify the Board within 30 days of a PAA, the TMA and TAFP do not necessarily oppose the Board proposing a rule requiring notifying the Board when a PAA terminates.

3. However, TMA and TAFP do not agree with the 30 day requirement for notifying the Board of the termination of a PAA set out in §193.10(e).

4. Although notifying the Board within 30 days of entering into a PAA is reasonable because patient safety is at issue as patients will be receiving medical care delegated by a physician. However, when a PAA is terminated, one would assume that patient care would not be at issue.

5. The notification period could be relaxed to a 90 day requirement which would allow physicians more time to comply with the rule.

6. Because some terminations of PAAs might be caused by disruptive event, such as member of staff leaving the practice, 90 would provide a practice focusing on quality of care and continuity of care during the immediate 90 day period following termination of a PAA.

Commenter: TSA

1. SB 406 added §157.0513 to the Medical Practice Act. This section requires the Board, the Texas Board of Nursing, and the Texas Physician Assistant Board to develop a process to exchange information regarding the names and locations of physicians, advanced practice registered nurses, and physician assistants who have entered into prescriptive authority agreements.

2. The statute does not distinguish between the four recognized designations of advanced practice registered nurses (APRNs) who may become parties to prescriptive authority agreements (nurse practitioner, nurse-midwife, nurse anesthetist, and clinical nurse specialist). The statute requires the Board to maintain and make available to the public a searchable online list of physicians, advanced practice registered nurses, and physician assistants who have entered into prescriptive authority agreements.

3. Section 157.0513(b) authorizes the Board to open an investigation of a physician upon notice that it is investigating an APRN who is a party to a prescriptive authority agreement.

4. Certified registered nurse anesthetists are not excluded or excepted from the broad language of §157.0513 and SB 406 will require CRNAs who work in practice settings to become parties to prescriptive authority agreements. These practice settings include pain management clinics, physician offices, subject to statutes and rules regarding office based anesthesia, ambulatory surgical centers, and hospitals that choose to utilize prescriptive authority agreements in lieu of standing delegation orders or protocols.

5. The wording of SB 406 clearly reflects legislative intent to hold all physicians, APRNs, and physician assistants to common policies, procedures and standards.

6. The Board has proposed a rule, §193.10(d), which TSA believes is incompatible with the intent of SB 406 and the express language of the statute.

7. There is nothing in SB 406 or §157.058 of the Occupations Code that exempts or excludes CRNAs or

physicians who are parties to prescriptive authority agreements from the statute's registration requirement.

8. Excluding CRNAs from the registration mandate will hamper the Board and the Board of Nursing in their attempts to regulate prescriptive authority agreements and therefore possibly put patients at risk.

9. The Board of Nursing has published proposed rule 22 TAC §222.10 which states the Board of Nursing will immediately notify the Texas Medical Board when an APRN becomes the subject of an investigation involving the delegation and supervision of prescriptive authority.

10. The above rule applies equally to all APRNs, but the Board's approach leaves open the possibility that after the Board receives notice of an investigation from the Nursing Board of an investigation of a CRNA involving delegation of prescriptive authority, the Board will not be able to consider disciplinary action against the physician who delegated prescriptive authority to the CRNA because §196.10(d) exempted the physician from the requirement of registering the CRNA's name. This would undermine the intent of SB 406.

11. TSA recommends that the Board withdraw §193.10(d) from the proposed rules.

Commenter: CNAP

1. Section 193.10(c) should be amended to address physicians who delegate prescriptive authority in facility-based practices and the APRNs and PAs to whom they delegate. When APRNs and PAs apply for a permit so they can prescribe controlled substances, this online list is used by the Department of Public Safety to confirm that they have prescriptive authority. It is important that the list include not only those who use PAAs, but physicians using protocols in facility-based practices.

2. Proposed rule §193.10(d) should also be amended to address physicians who delegate prescriptive authority in facility-based practices and the APRNs and PAs to whom they delegate. To comply with the requirement for registration in §157.0511(b-2), Medical Practice Act, CNAP proposes language similar to what is in the current §193.6(f)(3), to read as follows:

"(d) A physician who delegates the prescribing or ordering of a drug or device in a facility-based practice under §193.9 must register with the board the name and license number of the advanced practice registered nurse or physician assistant to whom the delegation is made."

Responses to Comments on §193.10

The Board staff disagrees that the 90 days advocated by TNA in regard to §193.10(e) is a reasonable amount of time in which to inform the Board that a prescriptive delegation has been terminated, and maintains that 30 days provides a reasonable time period. The registration process will be electronic and informing the Board of a terminated PAA will take only minutes. The Board declines to amend the language of this rule as requested by the TNA.

The Board agrees with the comments submitted by TSA that CRNAs are not exempted from the requirement of registering with the Board prescriptive authority agreements outside of a hospital setting. However, the Board does not agree that §193.10(d) needs to be deleted. Rather, the language in §193.10 would be appropriate if placed under §193.13 related to the delegation to certified registered nurse anesthetists. The Board has accordingly moved the language in §193.10 into §193.13.

In response to CNAP's comments regarding §193.10(c) and (d), the Board believes that physicians who delegate prescriptive authority at a facility through the use of prescriptive authority agreements, rather than through protocols or standing orders, are already required to register the prescriptive authority agreement with the Board. These prescriptive authority agreements would be included in the public online searchable database. Therefore, there is no need to amend the language of §193.10(c). The proposed amendment to §193.10(d) is

inconsistent with the intent of SB 406, which requires only that the Board maintain a public searchable online database of physicians, APRNs, and PAs who have entered into prescriptive authority agreements. Accordingly the Board declines to amend §193.10.

Section 193.13. Delegation to Certified Registered Nurse Anesthetists

Commenters: TMA and TAFP

1. TMA and TAFP note that §193.13 essentially restates §157.058 of the Occupations Code and that SB 406 did not amend §157.058.

2. TMA and TAFP do not oppose proposed rule §193.13 as written.

3. Although some members of the community believe CRNAs are authorized to practice without delegation or supervisions, in Texas, CRNAs must act under the delegation and supervision of a physician.

4. TMA and TAFP encourage the Board to consider whether there is a need to create clarifying rules to make clear that CRNAs must act under the delegation and supervision of physicians.

Commenter: TSA

1. TSA agrees with the comments submitted by TMA and TAFP regarding proposed Chapter 193, particularly the comments related to §193.13.

2. There is confusion in the medical community as to whether CRNAs are allowed to practice without delegation and supervision by physicians.

3. TSA believes that Texas law and appropriate standards of care require physician delegation and supervision of CRNAs.

Commenter: TANA

TANA does not object to the provisions of §193.13 which basically restates the provisions of §157.058 of the Texas Occupations Code.

Response to Comments on §193.13

The comments do not oppose adoption of §193.13 as written. The Board staff believes that current Board rules related to the practice of CRNAs are sufficient and make clear that CRNAs must act under the delegation and supervision of a physician.

Section 193.17. Nonsurgical Medical Cosmetic Procedures

Commenter: Texas Association of Aesthetic Nurses

1. TAAN comments that §193.17 is unnecessary and will cause harm to public.

2. Registered nurses have been performing nonsurgical medical procedures under standing delegation orders from physician-medical directors for years.

3. Standing delegation orders provide physicians sufficient control and supervision over procedures being performed by registered nurses. Registered nurses also have access to medical directors through the phone, email, and text messaging.

4. Registered nurses should be allowed to perform procedures without a physician or mid-level being present at the facility.

5. Section (d)(2) creates an unnecessary burden on patients by requiring that a physician or mid-level provider be more involved than is necessary.

6. Section (d)(3) which allows "qualified unlicensed personnel" to perform procedures increases the risk of harm to patients.

7. Nurses have extensive training and are answerable to the Texas Board of Nursing.

8. TAAN believes that §193.17 should be changed to require individuals performing such procedures to be licensed.

9. TAAN asks the Board reconsider the rule, and change it to allow registered nurses to perform procedures without a physician or mid-level being present at the facility, or alternatively, to require individuals performing nonsurgical cosmetic procedures under a physician's supervision to be licensed.

Individual Comments:

The Board received approximately 105 comments from individuals, all opposed to the adoption of proposed rule §193.17. The comments opposing proposed rule §193.17 reflected several common objections, which are set out and summarized below. Several comments did not set forth a basis for opposition but rather simply stated the commenter's opposition to the adoption of §193.17.

1. Increased Cost. Several commenters voiced concerns that the rule would result in increased costs for cosmetic treatment, including botox and fillers. None of the commenters articulated reasons why or how the proposed rule would increase costs, but some seemed to suggest that the proposed rule, being a form of regulation, would automatically increase costs.

2. Infringement on Personal Freedoms. Many commenters stated that they were opposed to the proposed rule because it infringed on their personal freedoms. Several commenters stated that the rule would take away their freedom to see the cosmetic procedure provider of their choice.

3. Unnecessary Regulation by the Government. Several commenters stated they were opposed to the proposed rule because it represented unnecessary regulation by the government and the imposition of more government red tape.

4. RNs are Qualified. Many commenters stated that RNs are qualified to perform injections and the injections do not need to be done by PAs or Physicians. Some commenters stated their opinion that RNs were better at performing cosmetic injections than physicians and that they preferred getting injections from RNs.

5. Rule will Limit Choice of Injectors and Treatment Plans. Several commenters suggested that the result of the proposed rule would be to limit consumers' choice of injectors and treatment plans.

6. Proposed Rule will Interfere with Convenience. Several commenters stated that the current system is convenient for them and expressed their concerns that the rules would interfere with this current convenience and limit their treatment options.

7. Proposed Rule will Force Consumers to go the Black Market. Several comments expressed the opinion that the rules will result in increased costs which will force consumers who need cosmetic treatment to utilize "black market" services staffed by non-medical personnel.

8. Physical Examination is Unnecessary. Several commenters opined that the physical examination required under the proposed rules was not necessary for the purpose of providing cosmetic services. Other commenters suggested that they would not be comfortable undergoing a physical examination.

Response to Comments on §193.17

Nonsurgical medical procedures are the practice of medicine and involve risks of complication. The Board disagrees with TAAN that §193.17 will causes harm to the public. Rather, the rule will enhance public safety by insuring that a physician or mid-level provider will be present at a facility where cosmetic procedures are being performed to personally treat or supervise treatment of any complications arising from the procedure. The Board disagrees with TAAN that standing orders and protocols and the ability to access physicians or mid-level providers via phone or text are sufficient to protect public safety. The personal presence of a physician or mid-level provider at a facility where cosmetic procedures are being performed provides greater safety to patients than mere standing delegation orders and phone consultation.

The comments submitted by individuals involved either issues of economics (i.e., higher costs) or personal freedom. The rule is designed to protect patient health and safety through proper supervision and delegation to mid-level providers. The intent of the rule is to enhance and insure patient safety during nonsurgical cosmetic procedures, which are medical procedures with inherent risks. The Board disagrees with the comments and declines to make any changes to this rule at this time.

22 TAC §§193.1 - 193.10, 193.12

STATUTORY AUTHORITY

The repeals are adopted under the authority of Texas Occupations Code Annotated, §153.001, which provides authority for the Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on October 18, 2013.

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Mari Robinson, J.D.

Executive Director

Texas Medical Board

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Proposal publication date: September 13, 2013

For further information, please call: (512) 305-7016

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22 TAC §§193.1 - 193.20

STATUTORY AUTHORITY

The new sections are adopted under the authority of Texas Occupations Code Annotated, §153.001, which provides authority for the Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

§193.1.Purpose.

(a) The purpose of this chapter is to encourage the more effective utilization of the skills of physicians by establishing guidelines for the delegation of health care tasks to qualified non-physicians providing services under reasonable physician control and supervision where such delegation is consistent with the patient's health and welfare; and to provide guidelines for physicians in order that existing legal constraints should not be an unnecessary hindrance to the more effective provision of health care services. Texas Occupations Code Annotated, §§164.001, 164.052, and 164.053 empower the Texas Medical Board to cancel, revoke or suspend the license of any practitioner of medicine upon proof that such practitioner is guilty of failing to supervise adequately the activities of persons acting under the physician's supervision, allowing another person to use his license for the purpose of practicing medicine, or of aiding or abetting, directly or indirectly, the practice of medicine by a person or entity not licensed to do so by the board. The board recognizes that the delivery of quality health care requires expertise and assistance of many dedicated individuals in the allied health profession. The provisions of this chapter are not intended to, and shall not be construed to, restrict the physician from delegating administrative and technical or clinical tasks not involving the exercise of medical judgment, to those specially trained individuals instructed and directed by a licensed physician who accepts responsibility for the acts of such allied health personnel. The board recognizes that statutory law shall prevail over any rules adopted and that the practice of medicine is, under Texas Occupations Code Annotated §151.002 (13), defined as follows: A person shall be considered to be practicing medicine within the Medical Practice Act ("the Act"):

(1) who shall publicly profess to be a physician or surgeon and shall diagnose, treat, or offer to treat, any disease or disorder, mental or physical, or any physical deformity or injury, by any system or method, or to effect cures thereof; or

(2) who shall diagnose, treat, or offer to treat any disease or disorder, mental or physical or any physical deformity or injury by any system or method and to effect cures thereof and charge therefor, directly or indirectly, money or other compensation.

(b) Likewise, nothing in this chapter shall be construed as to prohibit a physician from instructing a technician, assistant, or nurse to perform delegated tasks so long as the physician retains supervision and control of the technician, assistant, or employee. Nothing in this chapter should be construed to relieve the supervising physician of the professional or legal responsibility for the care and treatment of those persons with whom the delegating physician has established a physician-patient relationship. Nothing in this chapter shall enlarge or extend the applicable statutory law relating to the practice of medicine, or other rules and regulations previously promulgated by the board.

§193.2.Definitions.

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

(1) Advanced practice registered nurse--A registered nurse approved by the Texas Board of Nursing to practice as an advanced practice nurse on the basis of completion of an advanced educational program. The term includes an advanced nurse practitioner, a nurse midwife, nurse anesthetist, clinical nurse specialist, and advanced practice nurse, as defined by Texas Occupations Code Annotated, §301.152.

(2) Authorizing physician--A physician or physicians licensed by the board who execute a standing delegation

order or prescriptive authority agreement.

(3) Controlled substance--A substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Groups 1, 1-A, or 2 through 4 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.

(4) 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, Schedules I-V or Penalty Groups I-IV of 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".

(5) Device--Means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner, as defined by §551.003 of the Occupations Code.

(6) Facility based practice site--A hospital, as defined by §157.051(6) of the Act and this chapter, or a licensed long-term care facility. A facility-based practice does not include a freestanding clinic, center or other medical practice associated with or owned or operated by, a hospital or licensed long-term care facility.

(7) Health professional shortage area (HPSA)--

(A) an urban or rural area of this state that:

(i) is not required to conform to the geographic boundaries of a political subdivision but is a rational area for the delivery of health services;

(ii) the secretary of health and human services determines has a health professional shortage; and

(iii) is not reasonably accessible to an adequately served area;

(B) a population group that the secretary of health and human services determines has a health professional shortage; or

(C) a public or nonprofit private medical facility or other facility that the secretary of health and human services determines has a health professional shortage, as described by 42 U.S.C. §254e(a)(1).

(8) Hospital--A facility that:

(A) is:

(i) a general hospital or a special hospital, as those terms are defined by §241.003, Health and Safety Code, including a hospital maintained or operated by the state; or

(ii) a mental hospital licensed under Chapter 577, Health and Safety Code; and

(B) has an organized medical staff.

(9) 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.

(10) 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, as defined by §551.003(25) of the Occupations Code.

(11) Physician Assistant--A person who is licensed as a physician assistant by the Texas Physician Assistant Board.

(12) Physician group practice--An entity through which two or more physicians deliver health care to the public through the practice of medicine on a regular basis and that is:

(A) owned and operated by two or more physicians; or

(B) a freestanding clinic, center, or office of a nonprofit health organization certified by the board under §162.001(b) of the Act (relating to Regulation by Board of Certain Nonprofit Health Corporations), that complies with the requirements of Chapter 162 of the Act.

(13) Physician's orders--The instructions of a physician for the care of an individual patient.

(14) Practice serving a medically underserved population--Refers to the following:

(A) a practice in a health professional shortage area;

(B) a clinic designated as a rural health clinic under 42 U.S.C. §1395x(aa);

(C) a public health clinic or a family planning clinic under contract with the Health and Human Services Commission or the Department of State Health Services;

(D) a clinic designated as a federally qualified health center under 42 U.S.C. §1396d(l)(2)(B);

(E) a county, state, or federal correctional facility;

(F) a practice:

(i) that either:

(I) is located in an area in which the Department of State Health Services determines there is an insufficient number of physicians providing services to eligible clients of federally, state, or locally funded health care programs; or

(II) is a practice that the Department of State Health Services determines serves a disproportionate number of clients eligible to participate in federally, state, or locally funded health care programs; and

(ii) for which the Department of State Health Services publishes notice of the department's determination in the Texas Register and provides an opportunity for public comment in the manner provided for a proposed rule under Chapter 2001, Government Code; or

(G) a practice at which a physician was delegating prescriptive authority to an advanced practice registered nurse or physician assistant on or before March 1, 2013, based on the practice qualifying as a site serving a medically underserved population.

(15) 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.

(16) Prescription drug--Means:

(A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

(17) Prescriptive authority agreement--An agreement entered into by a physician and an advanced practice registered nurse or physician assistant through which the physician delegates to the advanced practice registered nurse or physician assistant the act of prescribing or ordering a drug or device. Prescriptive authority agreements are required for the delegation of the act of prescribing or ordering a drug or device in all practice settings, with the exception of a facility-based practice, pursuant to §157.054 of the Act.

(18) 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. The term protocols is separate and distinct from prescriptive authority agreements as defined under the Act and this chapter. However, prescriptive authority agreements may reference or include the terms of a protocol(s). The protocols must be agreed upon and signed by the physician, the physician assistant and/or advanced practice registered nurse, reviewed and signed at least annually, maintained on site, and must contain a list of the types or categories of dangerous drugs and controlled substances available for prescription, limitations on the number of dosage units and refills permitted, and instructions to be given the patient for follow-up monitoring or contain a list of the types or categories of dangerous drugs and controlled substances that may not be prescribed. Protocols shall be defined to promote the exercise of professional judgment by the advanced practice registered nurse and physician assistant commensurate with their education and experience. The protocols used by a reasonable and prudent physician exercising sound medical judgment need not describe the exact steps that an advanced practice registered nurse or a physician assistant must take with respect to each specific condition, disease, or symptom.

(19) Standing delegation order--Written instructions, orders, rules, regulations, or procedures prepared by a physician and designed for a patient population with specific diseases, disorders, health problems, or sets of symptoms. Such written instructions, orders, rules, regulations or procedures shall delineate under what set of conditions and circumstances action should be instituted. These instructions, orders, rules, regulations or procedures are to provide authority for and a plan for use with patients presenting themselves prior to being examined or evaluated by a physician to assure that such acts are carried out correctly and are distinct from specific orders written for a particular patient, and shall be limited in scope of authority to be delegated as provided in §193.4 of this title (relating to Scope of Standing Delegation Orders). As used in this chapter, standing delegation orders do not refer to treatment programs ordered by a physician following examination or evaluation by a physician, nor to established procedures for providing of care by personnel under direct, personal supervision of a physician who is directly supervising or overseeing the delivery of medical or health care. As used in this chapter, standing delegation orders are separate and distinct from prescriptive authority agreements as defined in this chapter. Such standing delegation orders should be developed and approved by the physician who is responsible for the delivery of medical care covered by the orders. Such standing delegation orders, at a minimum, should:

(A) include a written description of the method used in developing and approving them and any revision thereof;

(B) be in writing, dated, and signed by the physician;

(C) specify which acts require a particular level of training or licensure and under what circumstances they are to be performed;

(D) state specific requirements which are to be followed by persons acting under same in performing particular functions;

(E) specify any experience, training, and/or education requirements for those persons who shall perform such orders;

(F) establish a method for initial and continuing evaluation of the competence of those authorized to perform same;

(G) provide for a method of maintaining a written record of those persons authorized to perform same;

(H) specify the scope of supervision required for performance of same, for example, immediate supervision of a physician;

(I) set forth any specialized circumstances under which a person performing same is to immediately communicate with the patient's physician concerning the patient's condition;

(J) state limitations on setting, if any, in which the plan is to be performed;

(K) specify patient record-keeping requirements which shall, at a minimum, provide for accurate and detailed information regarding each patient visit; personnel involved in treatment and evaluation on each visit; drugs, or medications administered, prescribed or provided; and such other information which is routinely noted on patient charts and files by physicians in their offices; and

(L) provide for a method of periodic review, which shall be at least annually, of such plan including the effective date of initiation and the date of termination of the plan after which date the physician shall issue a new plan.

(20) Standing medical orders--Orders, rules, regulations or procedures prepared by a physician or approved by a physician or the medical staff of an institution for patients which have been examined or evaluated by a physician and which are used as a guide in preparation for and carrying out medical or surgical procedures or both. These orders, rules, regulations or procedures are authority and direction for the performance for certain prescribed acts for patients by authorized persons as distinguished from specific orders written for a particular patient or delegation pursuant to a prescriptive authority agreement.

(21) Submit--The term used to indicate that a completed item has been actually received and date-stamped by the Board along with all required documentation and fees, if any.

§193.8.Prescriptive Authority Agreements: Minimum Requirements.

Prescriptive authority agreement must, at a minimum:

(1) be in writing and signed and dated by the parties to the agreement;

(2) state the name, address, and all professional license numbers of the parties to the agreement;

(3) state the nature of the practice, practice locations, or practice settings;

(4) identify the types or categories of drugs or devices that may be prescribed or the types or categories of drugs or devices that may not be prescribed;

(5) provide a general plan for addressing consultation and referral;

(6) provide a plan for addressing patient emergencies;

(7) state the general process for communication and the sharing of information between the physician and the advanced practice registered nurse or physician assistant to whom the physician has delegated prescriptive authority related to the care and treatment of patients;

(8) if alternate physician supervision is to be utilized, designate one or more alternate physicians who may:

(A) provide appropriate supervision on a temporary basis in accordance with the requirements established by the prescriptive authority agreement and the requirements of this subchapter; and

(B) participate in the prescriptive authority quality assurance and improvement plan meetings required under this section; and

(9) describe a prescriptive authority quality assurance and improvement plan and specify methods for documenting the implementation of the plan that includes the following:

(A) chart review, with the number of charts to be reviewed determined by the physician and advanced practice registered nurse or physician assistant; and

(B) periodic face-to-face meetings between the advanced practice registered nurse or physician assistant and the physician at a location determined by the physician and the advanced practice registered nurse or physician assistant.

(10) The periodic face-to-face meetings described by paragraph (9)(B) of this section must include:

(A) the sharing of information relating to patient treatment and care, needed changes in patient care plans, and issues relating to referrals;

(B) discussion of patient care improvement; and

(C) documentation of the periodic face-to-face meetings.

(11) The periodic face-to-face meetings shall occur as follows:

(A) If during the seven years preceding the date the agreement is executed, the advanced practice registered nurse or physician assistant was not in a practice that included the exercise of prescriptive authority with required physician supervision for at least five years:

(i) at least monthly until the third anniversary of the date the agreement is executed; and

(ii) at least quarterly after the third anniversary of the date the agreement is executed, with monthly meetings held between the quarterly meetings by means of a remote electronic communications system, including videoconferencing technology or the Internet; or

(B) if during five of the last seven years preceding the date the agreement is executed, the advanced practice

registered nurse or physician assistant was in a practice that included the exercise of prescriptive authority with required physician supervision, but the agreement is not being entered into with the same supervising physician who delegated and supervised during the five year period:

(i) at least monthly until the first anniversary of the date the agreement is executed; and

(ii) at least quarterly after the first anniversary of the date the agreement is executed, with monthly meetings held between the quarterly meetings by means of a remote electronic communications system, including videoconferencing technology or the Internet; or

(C) if during five of the last seven years preceding the date the agreement is executed, the advanced practice registered nurse or physician assistant was in a practice that included the exercise of prescriptive authority with required physician supervision, and the agreement is being entered into with the same supervising physician who delegated and supervised during the five year period:

(i) at least quarterly; and

(ii) monthly meetings held between the quarterly meetings by means of a remote electronic communications system, including videoconferencing technology or the Internet.

(12) The prescriptive authority agreement may include other provisions agreed to by the physician and advanced practice registered nurse or physician assistant.

(13) If the parties to the prescriptive authority agreement practice in a physician group practice, the physician may appoint one or more alternate supervising physicians designated under paragraph (8) of this section, if any, to conduct and document the quality assurance meetings in accordance with the requirements of this chapter.

(14) The prescriptive authority agreement need not describe the exact steps that an advanced practice registered nurse or physician assistant must take with respect to each specific condition, disease, or symptom.

(15) A physician, advanced practice registered nurse, or physician assistant who is a party to a prescriptive authority agreement must retain a copy of the agreement until the second anniversary of the date the agreement is terminated.

(16) A party to a prescriptive authority agreement may not by contract waive, void, or nullify any provision of this section or §157.0513 of the Occupations Code.

(17) In the event that a party to a prescriptive authority agreement is notified that the individual has become the subject of an investigation by the board, the Texas Board of Nursing, or the Texas Physician Assistant Board, the individual shall immediately notify the other party to the prescriptive authority agreement.

(18) The prescriptive authority agreement and any amendments must be reviewed at least annually, dated, and signed by the parties to the agreement. The prescriptive authority agreement and any amendments must be made available to the board, the Texas Board of Nursing, or the Texas Physician Assistant Board not later than the third business day after the date of receipt of request, if any.

(19) The prescriptive authority agreement should promote the exercise of professional judgment by the advanced practice registered nurse or physician assistant commensurate with the advanced practice registered nurse's or physician assistant's education and experience and the relationship between the advanced practice registered nurse or physician assistant and the physician.

(20) This section shall be liberally construed to allow the use of prescriptive authority agreements to safely and effectively utilize the skills and services of advanced practice registered nurses and physician assistants.

§193.10.Registration of Delegation and Prescriptive Authority Agreements.

(a) The Board shall maintain and exchange information with the Texas Board of Nursing, and the Texas Physician Assistant Board, regarding the names locations and license numbers, of each physician, advanced practice registered nurse, and physician assistant who has entered into a prescriptive authority agreement.

(1) The Board shall immediately notify the Texas Physician Assistant Board and the Texas Board of Nursing when a license holder of the Board who has registered a prescriptive authority agreement(s) becomes the subject of an investigation involving the delegation and supervision of prescriptive authority, as well as the final disposition of any such investigation. Such notifications shall be made subject to, and without waiving any confidentiality provisions related to board investigations provided for under the Act and this Title.

(2) The Board shall maintain and share with the other boards a list of board license holders who have been subject to disciplinary action involving the delegation and supervision of prescriptive authority.

(b) Physicians who enter into prescriptive authority agreements with physician assistants or advanced practice registered nurses must register with the Board, within 30 days of signing the prescriptive authority agreement the following information:

(1) The name and license number of the physician assistant or advanced practice registered nurse to whom the delegation has been made;

(2) The date on which the prescriptive authority agreement was executed;

(3) The address(es) at which the advanced nurse practice registered nurse or physician assistant will be prescribing under the prescriptive authority agreement; and

(4) whether the prescriptive authority being exercised under the prescriptive authority agreement is being exercised in a practice servicing a medically underserved population.

(c) The board shall maintain and make available to the public, a searchable online lists of a of physicians, advanced practice registered nurses, and physician assistants who have entered into prescriptive authority agreements, and identify the physician, advanced practice registered nurse, or physician assistant, with whom each physicians, advanced practice registered nurse, or physician assistant has entered into a prescriptive authority agreement.

(d) A physician terminating a prescriptive authority agreement shall notify the board in writing within 30 days of such termination.

§193.13.Delegation to Certified Registered Nurse Anesthetists.

(a) In a licensed hospital or ambulatory surgical center a physician may delegate to a certified registered nurse anesthetist the ordering of drugs and devices necessary for a certified registered nurse anesthetist to administer an anesthetic or an anesthesia-related service ordered by the physician. The physician's order for anesthesia or anesthesia-related services does not have to be drug-specific, dose-specific, or administration-technique-specific. Pursuant to the order and in accordance with facility policies or medical staff bylaws, the nurse anesthetist may select, obtain, and administer those drugs and apply the appropriate medical devices necessary to accomplish the order and maintain the patient within a sound physiological status.

(b) A physician who delegates to a certified registered nurse anesthetist the ordering of drugs and devices necessary for the certified registered anesthetist to administer an anesthetic or an anesthesia-related service is not required to register the name and license number of the certified registered nurse anesthetist with the board.

(c) This section shall be liberally construed to permit the full use of safe and effective medication orders to utilize the skills and services of certified registered nurse anesthetists.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on October 18, 2013.

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Executive Director

Texas Medical Board

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Proposal publication date: September 13, 2013

For further information, please call: (512) 305-7016

PART 18. TEXAS STATE BOARD OF PODIATRIC MEDICAL EXAMINERS

CHAPTER 371. EXAMINATION AND LICENSURE

22 TAC §371.3

The Texas State Board of Podiatric Medical Examiners adopts the amendments to §371.3, regarding Fees, without changes to the proposed text as published in the August 23, 2013, issue of the *Texas Register* (38 TexReg 5413). The text will not be republished.

The amendments to §371.3 are adopted to cover the contingent revenue as stipulated by the 83rd Texas Legislature which required the board to assess or increase fees sufficient to generate during the FY2014-2015 biennium $93,942 in excess of $1,010,000 (Object Code 3562), contained in the Comptroller of Public Accounts' Biennial Revenue Estimate for fiscal years 2014 and 2015. Texas Occupations Code §202.153, Fees, states that the board by rule shall establish fees in amounts reasonable and necessary to cover the cost of administering this chapter.

No comments were received in response to the proposed amendments.

The amendments are adopted under Texas Occupations Code, §202.151, which provides the Texas State Board of Podiatric Medical Examiners with the authority to adopt reasonable or necessary rules and bylaws consistent with the law regulating the practice of podiatry, the laws of this state, and the law of the United States to govern its proceedings and activities, the regulation of the practice of podiatry and the enforcement of the law regulating the practice of podiatry.

The adopted amendments implement Texas Occupations Code §202.153, Fees.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on October 15, 2013.