

Proposed Adoption of Repeal of 22 Tex. Admin. Code Chapter 222, Pertaining to Advanced Practice Registered Nurses with Prescriptive Authority and New 22 Tex. Admin. Code Chapter 222, Pertaining to Advanced Practice Registered Nurses with Prescriptive Authority, Written Comments Received, Oral Comments Received at Public Hearing Held on September 13, 2013, and Board Responses to Comments

Background: Proposed new Chapter 222 and the proposed repeal of existing Chapter 222 were approved by the Board at its July 2013 meeting for submission to the *Texas Register* for public comment. The proposed repeal and new chapter were published in the *Texas Register* on August 9, 2013, and the comment period ended on September 9, 2013. The Board received several written comments and a request for a public hearing. A public hearing was held on September 13, 2013. A copy of the written comments received are attached as Attachment "A". A summary of the written comments and comments received at the public hearing, along with Staff's proposed responses to those comments, are attached as Attachment "B". Staff's proposed revisions to new Chapter 222 based upon comments received are attached as Attachment "C". Chapter 222, as proposed, is attached as Attachment "D", for comparison purposes.

Board Action: Move to adopt proposed new 22 Tex. Admin. Code Chapter 222, pertaining to *Advanced Practice Registered Nurses with Prescriptive Authority*, with changes, as set out in Attachment "C". Further, authorize Staff to publish the summary of comments and response to comments attached hereto as Attachment "B".

Additionally, move to adopt the proposed repeal of 22 Tex. Admin. Code Chapter 222, pertaining to *Advanced Practice Registered Nurses with Prescriptive Authority*, as proposed in the *Texas Register* on August 9, 2013, without changes.



COALITION FOR NURSES IN ADVANCED PRACTICE

P. O. Box 86 • Cedar Park, TX 78630

(512) 694-8349 • www.cnaptexas.org

September 10, 2013

Mr. James W. Johnston
General Counsel
Texas Board of Nursing
333 Guadalupe, Suite 3-460
Austin, Texas 78701

Re: Proposed rules at 22 TAC §§216.3
(*Texas Register* – August 16, 2013)

Delivered via e-mail: dusty.johnston@bon.texas.gov

Dear Mr. Johnston:

At its July 26, 2013, board meeting, the Coalition for Nurses in Advanced Practice (CNAP) reviewed the Board of Nursing's (BON) proposed new rules at 22 TAC §216.3, as well as the proposed rules at 22 TAC §§222.1 - 222.10. CNAP will submit comments to the BON in support of the proposed rule at 22 TAC §§222.3 (b) requiring an additional three hours of continuing education relating to prescribing controlled substances within the preceding biennium.

The CNAP Board also supports the BON's proposed rule at 22 TAC §216.3 (c) (3) that requires APRNs with prescriptive authority who prescribe controlled substances to complete at least three additional contact hours of continuing education relating to prescribing controlled substances. CNAP thinks the additional three hours of continuing education is consistent with the discussions among legislators during the 83rd Texas Legislature as they debated and passed Senate Bill 406. As a supporter of SB 406, CNAP believes the additional three hours of continuing education helps APRNs continue to treat patients with the utmost care and safety.

CNAP requests that the implementation of the new rules requiring an additional three hours of continuing education become effective no earlier than January 1, 2015. This will give APRNs time to identify and complete the coursework necessary to comply with this new requirement.

Thank you for considering these comments on these proposed rules. Please do not hesitate to contact me at 512-917-8782 if you have any questions.

Sincerely,

Trish Conradt

Trish Conradt
Public Policy Director
CNAP

Cc: Jolene Zych
Kathy Hutto
Jennifer Fontana
CNAP Board



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September 13, 2013

Mr. James W. Johnston
General Counsel
Texas Board of Nursing
333 Guadalupe, Suite 3-460
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Re: Proposed rules at 22 TAC §§222.1 - 222.10
(*Texas Register* – August 9, 2013)

Delivered via e-mail: dusty.johnston@bon.texas.gov

Dear Mr. Johnston:

At its July 26, 2013, board meeting, CNAP reviewed the Board of Nursing's (BON) proposed new rules at 22 TAC §§222.1 - 222.10. CNAP offers the following comments on the proposed rules based on that discussion:

- At proposed §222.3 (b) (*Renewal of Prescriptive Authority*), the proposed rules add a sentence requiring APRNs with prescriptive authority to prescribe controlled substances to attest "to completing at least three additional contact hours of continuing education related to prescribing controlled substances within the preceding biennium." CNAP supports the proposal to require an additional three hours of continuing education for APRNs who have the prescriptive authority to prescribe controlled substances. However, some minor changes are recommended so APRNs are clear as to the requirements for continuing education and when the new requirement takes effect.

Proposed §222.3 (b) has two components: requiring an APRN to attest to (1) five hours of continuing education related to pharmacotherapeutics, a requirement that already exists in §216.3(c)(3), and (2) three hours of continuing education related to controlled substances, a requirement being added to §216.3(c)(3) by rules proposed by the Board on August 16, 2013. An effective date for the additional three hours needs to be added to the rules. It is not reasonable to expect APRNs seeking to maintain their prescriptive authority will have the necessary three hours when this rule is adopted. Also, proposed §222.3(c) states that the above requirements are in addition to the continuing education required under Chapter 216, a statement that is true if it applies only to §216(c)(1) and (2) pertaining to the twenty hours of continuing education that all APRNs must have. For clarity, we recommend §222.3 (b) and (c) be amended as highlighted in red below:

- §222.3 (b) The APRN seeking to maintain prescriptive authority shall attest, on forms provided by the Board, to completing at least five contact hours of continuing education in pharmacotherapeutics within the preceding biennium, as required in §216.3(c)(3). After January 1, 2015, those APRNs seeking to maintain prescriptive authority who order or prescribe controlled substances shall attest, on forms provided by the Board, to completing at least three additional contact hours of continuing education related to prescribing controlled substances within the preceding biennium, as required in §216.3(c)(3).
(c) The continuing education requirements in subsection (b) of this section shall be in addition to continuing education required under §216(c)(1) and (2) of this title (relating to Continuing Competency).
- At proposed §222.4 (*Minimum Standards for Prescribing or Ordering Drugs and Devices*), the rule at subsection (a)(2) and (3) should be amended to reflect that APRNs must comply with the chart review requirements in the prescriptive authority agreement or the requirements in the facility-based written protocols or other written authorization, not both. We suggest this section now read as highlighted in red below:
 - §222.4 (a) The APRN with a valid prescription authorization number shall:
 - (1) order or prescribe only those drugs or devices that are:
 - (A) authorized by a prescriptive authority agreement or, if practicing in a facility-based practice, authorized by either a prescriptive authority agreement or protocols or other written authorization; and
 - (B) ordered or prescribed for patient populations within the accepted scope of professional practice for the APRN's license; and
 - (2) comply with the requirements for chart reviews specified in the prescriptive authority agreement and periodic face to face meetings set forth in this chapter; and or
 - (3) comply with the requirements set forth in protocols or other written authorization if ordering or prescribing drugs or devices under facility-based protocols or other written authorization.
- At proposed §222.5 (*Prescriptive Authority Agreement*), subsection (a) of the rule states that the “prescriptive authority agreement is “the” mechanism by which an APRN is authorized to order or prescribe drugs or devices.” CNAP recommends that “the” be changed to an “a” to reflect the intent of SB 406 that APRNs in facility-based practices can also use protocols or other written authorizations in lieu of a prescriptive authority agreement (PAA). The lack of changes to §157.058 and the minimal changes to §157.054, Occupations Code, in SB 406 were intended to ensure a mechanism for CRNAs and other hospital-based APRN practices to continue as they currently practice. This is also recognized in the preamble to these rules where a prescriptive authority agreement is described as “a mechanism”. This proposed change is highlighted in red below:

- §222.5. Prescriptive Authority Agreement. (a) The prescriptive authority agreement is ~~the a~~ mechanism by which an APRN is delegated the authority to order or prescribe drugs or devices by a physician.
- CNAP recommends amending proposed §222.5(b)(1) (*Prescriptive Authority Agreement*) by striking the definition of “good standing,” as proposed and substituting the definition below. As proposed, the definition of “good standing” would prohibit an APRN from being a party to a prescriptive authority agreement if the BON opened an investigation involving the APRN. This, in effect, would prohibit the APRN from prescribing or ordering drugs except in facility-based practices. Since most complaints do not result in a finding that the APRN violated the Nursing Practice Act, and the majority of complaints do not relate to the APRN's competence in prescribing, it would be inappropriate to prohibit an APRN from prescribing before the Board actually took any disciplinary action against the APRN and determined that the APRN was not competent to prescribe or order drugs and medical devices. The following better accomplishes the intent of SB 406.
 - §222.5 (b) An APRN with prescriptive authority and a physician are eligible to enter into or be parties to a prescriptive authority agreement only if the APRN:
 - (1) holds an active license to practice in this state that is in good standing. For purposes of this Chapter, "good standing" means that the advanced practice registered nurse's license has not been suspended and the Board of Nursing has not taken disciplinary action that prohibits the nurse from executing a prescriptive authority agreement.
- At proposed §222.5 (c)(8), CNAP recommends a change in the order of the words to more closely reflect the statute so the reader knows immediately that designating an alternate physician or physicians is not required. This proposed change is highlighted in red below:
 - (8) if an alternate physician arrangement is to be utilized, designate one or more alternate physicians who may participate in the execution of the prescriptive authority agreement in accordance with the rules of the Texas Medical Board if an alternate physician arrangement is to be utilized; and .
- At proposed §222.5 (f), the rule appears to limit the participation of alternate physicians in quality assurance meetings to those in physician group practices. Although Section 157.0512(h) is limited to a physician group practice, Section 157.0512(e)(8) is more broadly written. Therefore, CNAP recommends the proposed change as highlighted in red below:
 - §222.5 (f) The APRN shall participate in quality assurance meetings with an alternate physician in a physician group practice if the an alternate

physician has been designated ~~to conduct and document the meeting in the prescriptive authority agreement.~~

- At proposed §222.6 (*Prescribing at Facility-Based Practice Sites*), we recommend deleting “sites” in the title and the text of subsection (a) as that definition has been removed from statute and your proposed rules.

Also, at proposed §222.6(a)(1), we recommend deleting the language that a prescriptive authority agreement must meet the requirements of “this section” as it is the APRN who must meet the requirements, not the document. Also, if it is the Board’s intent that any written authorization used for prescriptive authority is in accordance with facility policy and reviewed annually, a modification in formatting would add clarity. These proposed changes are highlighted in red below:

- §222.6 Prescribing at Facility-Based Practice Sites.
 - (a) When ordering or prescribing a drug or device at a facility-based practice site, the APRN with prescriptive authority shall:
 - (1) maintain either a prescriptive authority agreement that meets the requirements of this section or protocols or other written authorization:
 - (A) developed in accordance with facility medical staff policies; and
 - (B) reviewed the authorizing documents with the appropriate medical staff at least annually;

- At proposed §222.7 (*Orders and Prescriptions for Non-prescription Drugs, Dangerous Drugs, and Devices*) we recommend deleting the last sentence as it deals with prescribing controlled substances and appears inappropriate in this section. This proposed change is highlighted in red below:

- §222.7. Orders and Prescriptions for Non-prescription Drugs, Dangerous Drugs, and Devices. APRNs with full licensure and valid prescription authorization numbers are eligible to order or prescribe non-prescription drugs, dangerous drugs, and devices, including durable medical equipment, in accordance with the standards and requirements set forth in this chapter. ~~APRNs with full licensure and valid prescription authorization numbers are not eligible to order or prescribe controlled substances unless they meet the applicable requirements of this rule.~~

- At proposed §222.8 (*Orders and Prescriptions for Controlled Substances*), subsections (a) and (d) seem redundant. CNAP suggests that (d) be deleted in favor of (a).
- At proposed §222.10 (*Enforcement*), subsection (c) refers to the BON notifying Texas Medical Board (TMB) and Texas Physician Assistant Board (TPAB) when

an APRN becomes the subject of an investigation regarding delegation of prescriptive authority. CNAP suggests that a new subsection (d) be added, as highlighted in red below, to require notification of the TPAB only when a PA is a party to a PAA involving an APRN subject to investigation. If there is not a PA included in the PAA, notification by the BON of the TPAB appears to be unnecessary paperwork for both agencies with no benefit to the public.

- (c) The Board shall immediately notify the Texas Medical Board and the Texas Physician Assistant Board:
 - (1) when an APRN licensed by the Board becomes the subject of an investigation involving the delegation and supervision of prescriptive authority; and
 - (2) upon the final disposition of an investigation involving an APRN licensed by the Board and the delegation and supervision of prescriptive authority.
- (d) If no physician assistant is party to the prescriptive authority agreement of an advanced practice registered nurse, the Board is not required to notify the Texas Physician Assistant Board.
- Also, at proposed §222.10 (*Enforcement*), subsection (f) references “sign prescription drug orders” and this should be “order or prescribe” to be consistent with SB 406. This proposed change is highlighted in red below:
 - (f) The practice of the APRN approved by the Board to ~~sign prescription drug orders~~ order and prescribe is subject to monitoring by the Board on a periodic basis.
- In the rules proposed by the Texas Medical Board, the term “authorizing physician” was defined in §193.2(2) to include a physician delegating prescriptive authority. For consistency, CNAP recommends this term be used to replace “collaborating physician” in Sections 222.1(23) and 222.4(b)(10) and “delegating physician” in Sections 222.6 and 222.8(b)(2) and (3).

Thank you for considering these comments and suggested changes to these proposed rules. We appreciate the hard work by the Board, staff and Advanced Practice Nursing Advisory Committee to develop these rules and look forward to working with you as they progress. Please do not hesitate to contact me at 512-917-8782 if you have any questions.

Sincerely,



Trish Conradt
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cc: Jolene Zych
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September 5, 2013

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Re: Proposed 22 TAC Chapter 222

Dear Mr. Johnston:

Please accept the following comments to the proposed new chapter, 22 TAC Chapter 222, on behalf of the Texas Association of Nurse Anesthetists (“TANA”):

1. Proposed change to §222.5(a):

The prescriptive authority agreement is ~~the~~ a mechanism by which an APRN is delegated the authority to order or prescribe drugs or devices by a physician.

Comment: TANA recommends this change for the reason that SB406 did not alter the provisions of Section 157.058 of the Texas Occupations Code which governs the delegation of the ordering of the drugs and devices necessary for a certified registered nurse anesthetist (“CRNA”) to administer an anesthetic or an anesthesia-related service ordered by a physician. Therefore, for CRNAs, a prescriptive authority agreement is *a* mechanism by which the CRNA may be delegated the authority to order or prescribe drugs or devices by a physician. However, a CRNA is not required to obtain a prescriptive authority agreement and may continue to obtain delegated authority for the ordering of the drugs and devices necessary for the CRNA to administer an anesthetic or an anesthesia-related service ordered by a physician pursuant to Section 157.058 of the Texas Occupations Code.

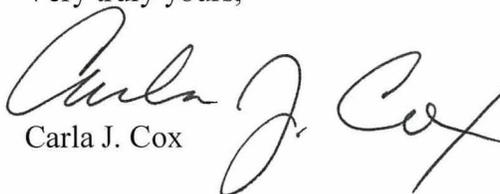
2. Proposed addition of subsection (m) to §222.5 to read as follows:

(m) A nurse anesthetist to whom a physician has delegated the ordering of drugs and devices necessary for the nurse anesthetist to administer anesthesia or anesthesia-related services, including pre-operative, post-operative, and consultative services, pursuant to Section 157.058 of the Texas Occupations Code is not required to obtain a prescriptive authority agreement for the ordering of prescription or non-prescription drugs, dangerous drugs, or controlled substances.

Comment: TANA recommends the addition of subsection (m) in order to make it clear that SB406 does not require a CRNA to practice pursuant to a prescriptive authority agreement but that CRNAs may continue to order drugs and devices necessary to administer anesthesia and anesthesia-related services pursuant to Section 157.058 of the Texas Occupations Code.

TANA thanks the Board for its consideration of these comments.

Very truly yours,


Carla J. Cox

cc: Jolene Zych, jolene.zych@bon.texas.gov



Physicians Caring for Texans

September 9, 2013

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RE: Proposed rules 22 TAC sections 222.1-222.12, Advanced Practice Registered Nurses with Prescriptive Authority, published in August 7, 2013 *Texas Register*

The Texas Medical Association (TMA) is a private, voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, our maxim continues in the same direction: "Physicians Caring for Texans." TMA's diverse physician members practice in all fields of medical specialization.

On behalf of TMA's 47,000 members, we write to provide comments to the Board of Nursing proposed revisions to Chapter 222, Texas Administrative Code, regarding advanced practice registered nurses (APRNs) with prescriptive authority. The proposed rules would implement SB 406, which is a bill that was negotiated and agreed upon by TMA, Texas Academy of Family Physicians, Texas Association of Physician Assistants, and the Texas Nurses Association.

SB 406 reaffirms, without question, that the prescribing of drugs and devices is the practice of medicine. The practice of medicine is limited to those individuals who the Texas Medical Board has licensed to practice medicine. Physicians may delegate the prescribing and ordering of drugs or devices, but any such delegation must be appropriately supervised by a physician in accordance with the standard of care. Although SB 406 repealed site-based requirements for supervision, it did not minimize the fundamental requirement of appropriate supervision—in fact, SB 406 replaces an arbitrary system based on location and percentages with a system that is custom made for the individual physician and APRN based on reasonableness and appropriateness. The prescriptive authority agreement (PAA) is a required document by which a physician delegates the prescribing and ordering of certain drugs or devices, and by which various elements of the relationship and supervision are addressed and documented. Although SB 406 includes elements of the PAA that must be addressed, as well as a minimum frequency of quality assurance meetings, the PAA may include more elements, more requirements, and more frequent quality assurance meetings as determined by a delegating and supervising physician.

TMA supports the concept of a physician-led, patient-focused, health care team as a way to provide greater access to care. Ultimately, however, the responsibility for coordinating, supervising, and managing the team rests with the physician.

TMA has the following specific comments to the proposed rules:

Section 222.1 Definitions

“Advanced Health Assessment,” “Advanced Practice Registered Nurse,” and “Diagnosis and Management Course”

TMA is opposed to the proposed definitions of “advanced health assessment,” “advanced practice registered nurse,” and “diagnosis and management course.” Each of these three proposed definitions implies that an APRN has the authority to make a medical diagnosis. TMA opposes use of the word “diagnosis” in these proposed definitions, because making a medical diagnosis is beyond the scope of nursing in Texas.

The Texas Board of Nursing (board) has proposed a definition for “advanced health assessment” as a course that offers content to allow students to “gain the knowledge and skills needed to perform comprehensive assessments to acquire data, *make diagnoses* of health status, and formulate effective clinical management plans.” It is inappropriate to define a term in the proposed rules which would allow nurses to gain the knowledge and skill needed to perform an act which they are prohibited by law from performing.

Additionally, the board is proposing a definition for “advanced practice registered nurse” to include a registered nurse who “is educationally prepared to assume responsibility and accountability for health promotion and/or maintenance, as well as the assessment, *diagnosis*, and management of patient problems...” See proposed 222.1(4)(E).

Finally, the board is also proposing a definition for “diagnosis and management course” which would offer both “didactic and clinical content in clinical decision-making and *aspects of medical diagnosis* and medical management of diseases and conditions.” Again, it is inappropriate to imply that a nurse can make a medical diagnosis, and misleading to train nurses to perform an act that the Nurse Practice Act prohibits.

Diagnosis is the practice of medicine. In Texas, no one is allowed to practice medicine without a license from the Texas Medical Board. TEX. OCC. CODE § 155.001 (West 2004). In the Medical Practice Act, “practicing medicine” means,

“the diagnosis, treatment or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who: (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services.”

TEX. OCC. CODE § 151.002(a)(13) (Vernon’s 2010).

The Legislature did not intend nurses to diagnose. Indeed, the Nurse Practice Act *specifically excludes diagnosis* from the nursing scope of practice. TEX. OCC. CODE § 301.002(2). Although licensed nurses are authorized to “observe,” “assess,” “intervene,” “evaluate,” and “rehabilitate”, professional nursing “*does not include acts of medical diagnosis...*” *Id.* The Texas Board of Nursing does not have the authority to expand, by rule, a licensee’s scope of practice beyond that authorized by the Legislature. TMA therefore and urges the board to remove reference to diagnosis from the definitions of “advanced health assessment,” “advanced practice registered nurse,” and “diagnosis and management course.”

TMA is also concerned with the proposed definition of “diagnosis and management course” in that it states that supervised clinical practice “must” include the opportunity to provide pharmacological and non-pharmacological management of diseases... This statement is misleading in that the APRN may only prescribe drugs or devices under the delegation and supervision of a physician. If a physician does not delegate this act, or other acts which are the practice of medicine, then the APRN is not authorized to perform such acts. Therefore, the word “must” should be changed to “may,” and reference should also be made to required delegation and supervision.

“Facility-Based Practice Site”

A definition for “facility-based practice site” is important to include in the proposed rules, however, the proposed definition should be written to be consistent with the intent of SB 406 and consistent with TMB rules. In that regard, TMA strongly suggests adding the following language to the definition: “*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.*” This language is included in TMB’s proposed definition for “facility-based practice site” and is consistent with the intent of SB 406.

“Prescribe or Order a Drug or Device”

The board has proposed a definition of “prescribe or order a drug or device” which is broader than the definition provided in SB 406, and TMA recommends using the definition exactly as it appears in SB 406. Currently the nursing board rules contain a definition for “prescribing” and for “signing a prescription drug order.” The latter definition specifies that the APRN must be designated to the Texas Medical Board by the delegating physician as a person delegated to sign a prescription. The proposed definition, however, is silent as to the requirement of delegation, and it suggests a level of independence by stating that an APRN may be the one to “determine the dangerous drugs or controlled substances or devices that shall be used or administered.” The APRN does not have the independent practice to make such a determination—the determination will be delegated by a physician, and will be made based on the specific drugs or devices that an APRN is authorized to prescribe pursuant to delegation and supervision.

Furthermore, SB 406 deleted the term “carrying out or signing a prescription drug order” and replaced it with “prescribing or ordering a drug or device.” This change was not intended to be a substantive change. In fact, during bill negotiations among the stakeholders, and during hearings on the bill, the question was asked regarding whether this change was substantive—the answer was always an unequivocal “no.” Therefore, the board should not suggest a substantive change in its definition. TMA recommends that the following definition be used, which is the definition provided in SB 406: “prescribe or order a drug or device means prescribing or ordering a drug or device, including the issuing of a prescription drug order or a medication order.”

“Protocols or Other Written Authorization”

TMA has concerns with use of the term “collaborating physician” in the board’s proposed definition of “protocols or other written authorization.” The Legislature has shown that Texas does not authorize prescriptive authority to APRNs through a “collaboration” model, but rather any such authority is granted through delegation and supervision. Use of the term “collaborating physician” is misleading and confusing. There are states that allow prescriptive authority through collaboration, but Texas is not one of them. TMA therefore recommends that the board replace the word “collaborating” with “delegating.” TMA supports a physician led team approach to patient care, but it must be clear that the team is physician led, not physician collaborated.

“Special Hospital”

The definition of “special hospital” is generally consistent with SB 406, but it contains additional language that could be misleading. SB 406 references section 241.003, Health & Safety Code to define “special hospital.” It appears that the board has tracked the language from section 241.003 in its proposed definition. The proposed definition, however, adds language pertaining to a medical staff in regular attendance, “as required by the rules of the Department of State Health Services.” This additional language is not in section 241.003. Section 241.003 requires a medical staff in regular attendance, and does not refer to DSHS requirements. The requirement for a medical staff in regular attendance flows from statute, not from DSHS. Furthermore, there are requirements that may apply, such as Joint Commission standards, in addition to any requirements by DSHS. Therefore, TMA recommends removing this additional qualifying language.

Section 222.2 Approval for Prescriptive Authority

Pursuant to section 222.2(a)(2), to be issued a prescription authorization number, a registered nurse must verify successful completion of graduate level courses in “diagnosis and management of diseases and conditions within the role and population focus area.” As previously stated, TMA opposes the board’s implication that a nurse is authorized to make a medical diagnosis. Licensed nurses are authorized to “observe,” “assess,” “intervene,” “evaluate,” and “rehabilitate”, but professional nursing “*does not include acts of medical diagnosis....*” TEX. OCC. CODE § 301.002(2). Therefore, TMA urges the board to remove reference to diagnosis in section 222.2(a)(2).

Section 222.3 Renewal of Prescriptive Authority

Section 222.3 requires an APRN to obtain three additional hours of continuing education related to prescribing controlled substances within the preceding biennium, if the APRN is seeking prescriptive authority for controlled substances. TMA supports this additional continuing education requirement, and suggests that the required number of hours could be higher. APRNs with prescriptive authority should be educated regularly regarding the potential for controlled substance abuse and diversion. Opioid addiction is a national epidemic and all health care providers involved in the prescribing, administering, or dispensing of controlled substances should be well apprised of the issues involved, including appropriate safeguards, regulations, and standard of care.

Section 222.4 Minimum Standards for Prescribing or Ordering Drugs and Devices

Section 222.4(a)(2) requires an APRN to “comply with the requirements for chart reviews specified in the prescriptive authority agreement and periodic face to face meetings set forth in this chapter.” The periodic face to face meetings are to be set forth in the *prescriptive authority agreement*, not in the nursing board rules. The rules should be written to reflect the fact that the elements of the prescriptive authority agreement which were provided in SB 406 are only *minimum* requirements. Section 157.0512(e) states the elements of a prescriptive authority agreement “at a minimum.” Section 157.0512(g) states that the prescriptive authority agreement may include other provisions agreed to by the physician and APRN or PA. Therefore, it is the prescriptive authority agreement, not the board’s rules and not statute, which provide the requirements for periodic face to face meetings. TMA recommends that the board reflect this fact in its rules, and in that regard replace “set forth in this chapter” with “set forth in the prescriptive authority agreement.”

TMA also has a concern with section 222.4(b)(10) in that it refers to a “collaborating physician.” As previously discussed, Texas does not authorize prescriptive authority for an APRN through collaboration. Texas has reaffirmed, pursuant to SB 406, that the prescribing of drugs or devices by an APRN or PA is only pursuant to the delegation and supervision of a physician. TMA therefore urges the board to remove reference to “collaborating physician” from its proposed rules, because it is inaccurate and misleading, and replace such terminology with “delegating physician.”

Section 222.5 Prescriptive Authority Agreement

TMA is generally supportive of proposed section 222.5, because it is generally consistent with SB 406. TMA does have some concerns with portions of section 222.5 that do not accurately reflect SB 406, however.

For example, TMA opposes section 222.5(c)(8) as written, because it inaccurately states that a prescriptive authority agreement may designate one or more alternate physicians who may participate in the “execution of the prescriptive authority agreement.” SB 406 permits a physician who is executing a prescriptive authority agreement, and *who is in a physician group practice* as defined by section 157.051, Occupations Code, to designate one or more alternate physicians who may “provide appropriate supervision on a temporary basis in accordance with the requirements established by the prescriptive authority agreement...and participate in the prescriptive authority quality assurance and improvement plan meetings...” See section 157.0512(e)(8). The proposed rule, however, is inaccurate in that it: 1) allows an alternate physician to “execute” the prescriptive authority agreement (which SB 406 does not permit); 2)

does not specify that alternate supervision is allowed only in a physician group practice; and 3) does not provide that the supervision is to be on a temporary basis. TMA therefore recommends that the board track the language of section 157.0512(e)(8) directly, such that the specifics that the statute provides are clearly provided in the rule.

TMA also has concerns with proposed section 222.5(d)(2)(B) because it does not clearly reflect that the minimums for periodic face to face meetings can be modified based *only* on previous involvement of prescriptive authority *with the same physician* who is executing the prescriptive authority agreement. See SB 406, Section 28 (“under the delegated prescriptive authority *of that physician...*”)(emphasis added). The Texas Medical Board has correctly interpreted SB 406, by requiring the same physician to be involved in the previous delegation. In order to accurately reflect the intent of SB 406, and to be consistent with TMB interpretation, TMA recommends that the board adopt the following language for section 222.5(d)(2)(B):

If during the seven years preceding the date the agreement is executed, the advanced practice registered nurse was supervised for at least five years in a practice that included the exercise of prescriptive authority with required physician supervision by the physician with whom the prescriptive authority agreement is entered:...

TMA supports proposed section 222.5(e), which states that a prescriptive authority agreement may include other provisions. This is a key component of SB 406 and the intent of the Legislature. The elements of the prescriptive authority agreement enumerated in SB 406 are only minimums, and the requirements of delegation and supervision will be tailored to the health care providers involved, in accordance with the standard of care. Therefore, it is important to note that these agreements will be custom made based on what is reasonable delegation and supervision under the circumstances.

Proposed section 222.5(f) should be clarified to reflect that an alternate physician, if any, must be designated “in the prescriptive authority agreement.” Therefore, TMA recommends adding “in the prescriptive authority agreement, after “has been designated” and before “to conduct and document” in subsection (f).

Section 157.0512(l), Occupations Code, states that a party to a prescriptive authority agreement may not by contract waive, void, or nullify any provision of section 157.012 or 157.0513. Section 222.5(i) of the board’s proposed rules, however, states that a party may not waive, void, or nullify any provision “of this rule.” TMA recommends adding “or section 157.012 or 157.0513, Occupations Code” to the proposed rule, so that it is clear that a party may not waive, void, or nullify the rules or these statutory sections.

Section 222.6 Prescribing at Facility-Based Practice Sites

Section 222.6 appears to be consistent with Section 157.054, Occupations Code. There seems to be one error in subsection (a)(1), however, in that there is a reference made to meeting the prescriptive authority agreement requirements “of this section.” The prescriptive authority agreement requirements are not proposed in section 222.6, but rather they are proposed in section 222.5 of the rules, so TMA recommends making reference to section 222.5 in this rule.

Section 222.7 Orders and Prescriptions for Non-Prescription Drugs, Dangerous Drugs, and Devices

Section 222.7 is concerning in that it does not reference the delegation and supervision by a physician to an APRN. It simply states that APRNs are eligible to order or prescribe non-prescription drugs, dangerous drugs, and devices. It also states that APRNs are not eligible to order or prescribe controlled substances unless they meet the applicable requirements of this rule. This rule should reference the requirement for delegation and supervision, prior to an eligible APRN being able to exercise prescriptive authority. Furthermore, the last sentence of the proposed rule reference the requirements “of this rule”, but it is the requirements of rule section 222.8 that should be met pertaining to controlled substances. TMA recommends that section 222.8 be reference in this proposed rule, and that the requirement of physician delegation and

supervision be referenced as well, because delegation and supervision is the foundation of APRN prescriptive authority in Texas.

In summary, TMA appreciates the opportunity to provide comment on the proposed rules. TMA supports the concept of a physician led, patient focused, health care team, and we are of the opinion that SB 406 supports that concept as well. We are optimistic that the board will consider our comments to the proposed rules, and make modifications in order to more closely align the board's rules with SB 406 and the rules of the TMB.

Sincerely,



Stephen L. Brotherton, MD
President, Texas Medical Association

cc:
Jolene Zych
Advanced Practice Nursing Consultant
Texas Board of Nursing
333 Guadalupe, Suite 3-460
Austin, Texas 78701



PRESENTED AT PUBLIC HEARING 9/13/2013

September 13 2013

James W. Johnston
General Counsel
Texas Board of Nursing
333 Guadalupe, Ste 3-460
Austin, Texas 78701

Jolene Zych
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Re: Comments on proposed Rule §222 as published at 38 Tex Reg 4989 (8/9/2013)

Dear Mr. Johnston and Ms. Zych:

The Texas Nurses Association submits the following comments on proposed Rule 222.

1. TITLE AND CONTENT OF CHAPTER 222

Recommended Change

1) Move the following BON Rules from Chapter 221 to Chapter 222 and reword as appropriate:

- §221.14 Nurse-Midwives Providing Controlled Substances
- §221.15 Provision of Anesthesia Services by Nurse Anesthetists in Licensed Hospitals or Ambulatory Surgical Centers
- §221.16 Provision of Anesthesia Services by Nurse Anesthetists in Outpatient Settings

and 2) amend title of Chapter 222 to read:

Prescribing, Ordering or Providing Drugs or Devices by Advanced Practice Registered Nurse

Rationale

SB 406 expanded the drugs an APRN may prescribe or order under a prescriptive authority agreement (“PAA”) or protocol to include controlled substances Schedule II (“CS II”) in certain settings. This may provide CNMs and CRNAs an additional delegation mechanism for ordering CS IIs in hospitals. TNA believes it would promote better understanding of the different delegation mechanisms if all the rules relating to physician delegation of prescribing, ordering, or providing drugs or devices to APRNs were set out in Chapter 222.

2. EFFECTIVE DATE FOR RULE

Recommendation:

Add a provision setting the effective date for the rule as November 1, 2013.

Rationale:

The proposed rule does not set out an effective date. Since the rule will implement the provisions of SB 406 which goes into effect November 1, 2013, TNA believes the effective date of the changes to Chapter 222 implementing SB 406 should be November 1.

3. EFFECTIVE DATE FOR CE REQUIREMENT FOR APRNs PRESCRIBING CONTROLLED SUBSTANCES

Recommended Change

Amend the second sentence in (b) to read:

Those APRNs seeking to maintain renewing prescriptive authority on or after January 1, 2015, who order or prescribe controlled substances shall . . .

Rationale

Proposed Rule 222.3(b) imposes a new requirement of three hours of continuing education for APRNs prescribing controlled substances but does not set out a start date for when APRNs must show compliance with this new requirement. TNA believes there needs to be sufficient lead time to allow for the continuing education offering to be developed and for APRNs to meet the new requirement. This lead time should be at least a year.

4. APRNs ELIGIBLE TO BE PARTIES TO A PRESCRIPTIVE AUTHORITY AGREEMENT.

Recommended Change

Amend Rule 222.5(b) to define good standing for purposes of eligibility to execute a PAA such that good standing is:

- 1) determined only on the basis of a final disciplinary action against an APRN and not on basis of opening of an investigation or filing of formal charges.
- 2) defined so that not every adverse action (regardless of severity) against an APRN's license or authorization categorically precludes an APRN from executing a PAA.

More specifically, amend definition of "good standing" in Rule 222.5(b) to read:

(b) An APRN with prescriptive authority and a physician are eligible to enter into or be parties to a prescriptive authority agreement only if the APRN:

(1) holds an active license to practice in this state ~~that~~ and the APRN is in good standing. ~~For purposes of this chapter,~~ An APRN is in good standing ~~means that if the nurse's license~~ APRN's nursing license(s) or authorization(s) is not encumbered or if encumbered, the APRN is permitted by board order to be a party to a prescriptive authority agreement. APRNs with a license or authorization encumbered as of 11/1/2013 shall be considered in

good standing if in compliance with any restriction or condition of probation imposed on the license or authorization. ~~in delinquent status and that there is no current disciplinary action, disciplinary probation, or pending investigation(s) on his/her nursing license(s) or authorization(s);~~

Rationale:

Medical Practice Act (MPA) §157.0512(b)(2)(A) requires an APRN be in good standing to execute a PAA. Proposed Rule 222.5(b)(1) defines “good standing” as “there is no current disciplinary action, disciplinary probation, or pending investigation(s) on his/her [APRN’s] nursing license(s) or authorization(s).” This definition would preclude an APRN from executing a PAA if there was any current adverse action against the APRN’s license or authorization or even if there is a pending investigation. TNA does not believe this interpretation of §157.0512(b)(2)(A) is the correct interpretation or one supported by the rules of statutory construction. TNA’s recommended wording is more consistent with §151.0512(b)(2)(A) and also adequately protects the public from an APRN who the board determines should not be prescribing or ordering drugs or devices. See Attachment A for a more detailed discussion of the appropriate interpretation of good standing.

TNA believes that it is not consistent with good public policy to place restrictions on a nurse’s practice based on the opening of an investigation or on the filing of formal charges. The Nursing Practice Act (NPA) §301.455 gives the board the authority to immediately suspend or restrict a nurse’s license if it believes the nurse’s practice poses an imminent threat to the public welfare. Adoption of a rule placing restrictions on a nurse’s license on the basis of a pending investigation or formal charges would be setting a bad precedent.

By addressing APRNs with adverse action pending on 11/1/2013, TNA’s recommended definition of “good standing” includes a mechanism for APRNs with adverse actions pending on 11/1/2013 to be able to execute a PAA. Otherwise, even a pending adverse action for a minor violation may prevent an APRN from executing a PAA. TNA proposes that an APRN with an adverse action pending on 11/1/2013 who is complying with any restrictions or conditions of probation as one mechanism to accomplish this. There may be other mechanisms that would also accomplish the desired result.

5. PRESCRIPTIVE AUTHORITY AGREEMENT AS NONEXCLUSIVE DELEGATION MECHANISM

Recommendation:

Reword Rule 222.5(a) so that does not imply that a PAA is the only delegation mechanism that can be used to authorize an APRN to prescribe or order drugs or devices.

Rationale

Describing a PAA as “the” mechanism by which an APRN is delegated the authority to order or prescribe implies that it is the only mechanism. In addition to a PAA, a protocol may also be used as the delegation mechanism in a facility-based practice and MPA §157.058 is an additional delegation available to CRNAs.

6. CREDIT FOR TIME PRACTICED WITH PHYSICIAN PRIOR TO NOVEMBER 1, 2013 WHEN CALCULATING FREQUENCY OF FACE-TO-FACE MEETINGS.

Recommended Change

Amend Rule 222.5(d)(2) by adding a new Subdivision (C) that reads:

(C) If during any period of time prior to November 1, 2013 the APRN practiced under the delegated prescriptive authority of the physician signing the prescriptive authority agreement, that period of time shall be included in calculating the third anniversary under Subdivision (A)(i) or the first anniversary under Subdivision (B)(i).

Rationale:

SECTION 28 of SB 406 authorizes credit for time the delegating physician and APRN practiced together (with APRN authorized to prescribe) prior to 11/1/13. Not addressing credit in Rule 222 may result in some APRNs not realizing the credit is available.

7. CRNAs ORDERING ANESTHESIA-RELATED DRUGS AND SERVICES

Recommended Change

Add a new Section 222.10 whose content tracks (except for addition of a beginning sentence) current Board Rule 221.16 and reads as follows and renumber current sections accordingly:

§222.10. CRNA's Ordering Anesthesia-Related Drugs and Devices

Notwithstanding any other section of this chapter:

(a) – (c) [current Rule 221.16 (a)-(c)]

Rationale

Prior to passage of SB 406, MPA Sec 157.058 addressed the delegation mechanism for CRNAs to order CS II anesthesia-related drugs. SB 406 provided potential additional mechanisms by permitting APRNs to prescribe CS II for hospital inpatients and hospital ER patients under protocols and PAAs. Consequently, there may be confusion about what delegation mechanism can be used to authorize CRNAs to order anesthesia-related drugs and services. Adding the recommended language will make explicit that the delegation mechanism allowed by MPA Sec 157.058 remains an option available to CRNAs. Except for the qualifier “Notwithstanding any other section of this chapter,” the content is identical to current Rule 221.15. However, TNA believes this issue is best addressed in Chapter 222 relating to prescribing or ordering drugs or devices. See also Item #1 above in which TNA recommends also moving Rules 216.14 and 216.14 to Chapter 222.

8. FACILITY-BASED PRACTICE – RULE 222.6

Recommended Change

1. Amend title by deleting “site” so title reads:

Prescribing at Facility-Based Practice Site

2. Explicitly state whether a PAA used at a facility-based practice must comply with **both** Rule 222.5 requirements for PAAs and Rule 225.6 requirements relating to delegation at facility-based practices. If a PAA is required to meet the requirements of both Rule 222.5 and Rule 222.6, TNA recommends Rule 222.6 be amended to read:

(a) An APRN with prescriptive authority, whose practice is facility-based at a hospital or licensed long term care facility may prescribe or order a drug or device as authorized by:

(1) a protocol or other written authorization that complies with the requirements of Subsection (b) of this section; or:

(2) a prescriptive authority agreement that complies with the requirements of both:

(i) Subsection (b) of this section; and

(ii) Section 222.4 (relating to PAAs)

(b) When an APRN prescribes or orders a drug or device at a facility-based practice, the prescribing or ordering must:

(1) be delegated:

(A) in a hospital, by a physician who is the medical director, the chief of medical staff, the chair of the credentialing committee, or a department chair, or a physician who consents to the request of the medical director or chief of the medical staff to delegate to the APRN;

(B) in a long term care facility, by a physician who is the medical director;

(2) occur in the facility in which the physician is the medical director, the chief of medical staff, the chair of the credentialing committee, or a department chair, or a physician who consents to the request of the medical director or chief of the medical staff to delegate to the APRN; and

(3) be for the care or treatment of only those patients for whom the patient's physician has given prior consent.

(c) Protocols or other written authorization is authorization to . . .

NOTE. Subsec. (c) repeats almost verbatim the definition of "protocol or other written authorization" set out in Rule 222.1 and it may not be necessary to set out twice. However, since Rule 222.6 is primary rule addressing protocols, if set out only once, Rule 222.6 may be the preferred location.

Rationale

TNA believes the reference to "site" in heading of Rule 222.6 should be deleted since SB 406 eliminated the "site-based" model and "site" terminology is not used in SB 406. For example, the term "site serving medically underserved populations" was changed to "practice serving underserved population." Unfortunately, SB 406 only amended individual subsections of MPA §157.054 so the title to §157.054 was not amended and the reference to "site" in the title was not changed. However, since under Sec. 311.024 of the Code Construction Act titles have no substantive effect, deleting the word "site" in the title to Rule 222.6 is consistent with the conceptual scheme reflected in SB 406.

SB 406 does not explicitly address the use of PAAs in facility-based practices. MPA §157.0512 does not limit the practices where a PAA can be used. MPA §157.054 neither explicitly permits nor precludes the use of a PAA at a facility-based practice. However, §157.054 authorizes delegation of prescribing and ordering at a facility-based practice only if certain requirements are met. TNA believes that the most plausible interpretation of SB 406 is that a PAA may be used as a delegation mechanism at a facility-based practice and

that if used must comply with the requirements of both §157.0512 (relating to PAAs) and §157.054 (relating to facility-based practices). If this is the correct interpretation of SB 406, TNA believes the BON rules should explicitly state that if a PAA is used at a facility-based practice it must meet the requirements of both Rule 222.5 and Rule 222.6.

9. DEFINITIONS

As general rule, TNA believes that it is desirable for the definitions in Rule 222 to track as closely as possible the definitions in SB 406 and when possible for the definitions used in the board rules and the medical board rules implementing SB 406 be the same or as similar as possible. The TMB's proposed rules are scheduled to be published in Texas Register today (9/13/2013) so will be available for comparison.

Recommended Changes

1. Consider simplifying or deleting following definitions

1) Advanced Practice Registered Nurse

TNA recommends definition be simplified to read:

Advanced practice registered nurse - a registered nurse licensed by the board to practice as an advanced practice registered nurse on basis of completion of an advanced educational program.

This recommended definition tracks definition of APRN in SB 406 and NPA §301.152. The purpose of the definition in Rule 222 should be to identify the nurses to whom Rule 222 applies. The definition in the proposed rules goes beyond that and sets out substantive criteria for how to qualify as an APRN. This type of definition may be appropriate in another rule but is not necessary for Rule 222.

2) Durable Medical Device

Delete. Definition is unnecessary since term "DME" is not ambiguous and is a term APRNs understand. DME is used in various Texas laws and rules relating to reimbursement for DMEs, and TNA cannot find the term defined by any of these laws or rules. TNA believes that DME can be used as an undefined term.

3) General Hospital

Delete. Unnecessary since distinction between a general and special hospital is not relevant to APRN prescribing or ordering drugs or devices.

4) Special Hospital

Delete. Unnecessary since distinction between a general and special hospital is not relevant to APRN prescribing or ordering drugs or devices.

2. Amend following definitions to more closely track how SB 406 defines or how TMB defines in its proposed rules.

1) Medication order

Proposed definition does not capture adequately aspect of medication order being an order to a hospital pharmacist to dispense a medication.

2) Protocol or other written authorization

TNA believes it would be desirable for the BON to review the TMB proposed definition to be sure the definitions are completely consistent. The definition of protocol in the TMA proposed rule states a PAA may reference a protocol. If the board incorporates this language into its definition, TNA recommends that it describe the protocol as a “clinical protocol or guideline.”

3. Consider adding following definitions as necessary or appropriate

1) APRN with prescriptive authority

See Item #10A below as possible need for defining.

2) Prescription drug order

May be needed to distinguish from “medication order”

3) Authorizing physician

Would be physician delegating the authority to an APRN to prescribe or order drugs or devices

10. NON-SUBSTANTIVE EDITS

The following are non-substantive edits that TNA believes might simplify Rule 222 or facility understanding of the Rule.

10a. Use of Consistent Standardized Terminology

It may be helpful if standardized terminology was identified and used throughout Rule 222 such as:

- 1) Unless context clearly indicates otherwise, whenever use “prescribe,” “prescription drug order,” or “drug,” replace with “order or prescribe,” “prescription drug orders or medication orders,” “drug or device,” etc.
- 2) Unless context clearly indicates otherwise, use “APRN with prescriptive authority” instead of varying terminology such as “APRN with valid prescription authorization number,” “APRN with full licensure and valid authorization number,” “APRN with full licensure,” etc.

10b. References to “Dispense” in Rule 222.10(a)(1), (2), (3) and (5)

It is not clear that APRNs “dispense” so not sure why referred to in rule. If term is referring to APRNs supplying drug samples, then TNA believes better to state explicitly.

10c. Redundancy

TNA believes there is some redundancy in Rule 222 that could be eliminated to make rule shorter and simpler.

- “Protocol or other written authorization” is defined in both Rule 222.1 and 222.6. Since term is used primarily in Rule 222.6, that may be best place to define.
- Requirement that cooperate with inspection and audit is set out in Rule 222.4(f) and Rule 222.10(b). The latter is probably the more appropriate place since relates to enforcement.

- Requirement that APRN comply with DPS and DEA requirements is set out in Rule 222.8(a) and (d).

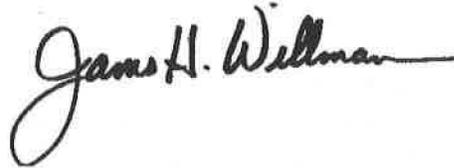
10d. Delete References to “Site”

Unless the context clearly indicates otherwise, TNA believes any reference to “site” should be deleted. SB 406 eliminated the “site-based” model and “site” terminology is not used in SB 406. For example, the term “site serving medically underserved populations” was changed to “practice serving underserved population.”

10e. Clarify New Continuing Education Requirement

Rule 222.3(c) states that the new requirement of three hours of continuing education in ordering or prescribing controlled substances is “in addition to continuing education required under Chapter 216.” TNA believes should be clarified that is in addition to any continuing education required to maintain the APRN’s registered nurse license.

Respectfully submitted,



James H. Willmann, JD
Director Governmental Affairs

cc. Kathy Thomas kthomas@bon.texas.gov
Jena Abel jable@bon.texas.gov

ATTACHMENT A
BACKGROUND ON APRN BEING IN GOOD STANDING TO EXECUTE
PRESCRIPTIVE AUTHORITY AGREEMENT

Section 157.0512(b)(2)(A) of the Medical Practice Act (“MPA”) states that to be eligible to execute or be a party to a prescriptive authority agreement (“PAA”), an APRN must hold an active license and be in “good standing.” Section 157.0512(b) reads:

*(b) A physician and an advanced practice registered nurse or physician assistant is **eligible to enter into or be parties to a prescriptive authority agreement only if:***

(1) if applicable, the Texas Board of Nursing has approved the advanced practice registered nurse's authority to prescribe or order a drug or device as authorized under this subchapter;

*(2) **the advanced practice registered nurse or physician assistant:***

*(A) **holds an active license to practice in this state as an advanced practice registered nurse or physician assistant, as applicable, and is in good standing in this state; and***

*(B) **is not currently prohibited by the Texas Board of Nursing or the Texas Physician Assistant Board, as applicable, from executing a prescriptive authority agreement; and***

(3) before executing the prescriptive authority agreement, the physician and the advanced practice registered nurse or physician assistant disclose to the other prospective party to the agreement any prior disciplinary action by the board, the Texas Board of Nursing, or the Texas Physician Assistant Board, as applicable.

[Emphasis added]

Proposed Rule 222.5(b) implements this provision.

*(b) An APRN with prescriptive authority and a physician are eligible to enter into or be parties to a prescriptive authority agreement only **if the APRN:***

*(1) **holds an active license to practice in this state that is in good standing. For purposes of this chapter, good standing means that the nurse's license is not in delinquent status and that there is no current disciplinary action, disciplinary probation, or pending investigation(s) on his/her nursing license(s) or authorization(s);***

*(2) **is not currently prohibited by the Board from executing a prescriptive authority agreement; and***

[Emphasis added]

Under this interpretation of §157.0512(b)(2)(A), any APRN, who has an encumbered license or is the subject of a pending investigation, will not be in good standing and consequently, ineligible to execute or be a party to a PAA.

Section 157.0512(b) is best interpreted so that not all encumbrances on a license make the APRN ineligible to execute a PAA. First, the fact that “good standing” applies to the APRN and not the license is significant. There is a difference in a practitioner being in good standing and their license being in good standing. An APRN complying with all the conditions of probation

can reasonably be said to be in good standing even though would probable say the license is not. The same would be true of an APRN participating in the Texas Peer Assistance Program for Nurses (“TPAPN”). More importantly, if “good standing” is construed as applying to any encumbrance on the APRN’s license, then §157.0512(b)(2)(B) becomes somewhat meaningless or at least superfluous. If any encumbrance makes the APRN ineligible, then the requirement that the APRN “is not currently prohibited by the BON from executing a PAA” becomes largely redundant.

Not permitting an APRN to prescribe with an encumbered license has significant practical implications. The length of time in TPAPN for an APRN or being on probation is likely to be at least 3-5 years. It could be difficult for an APRN to resume prescribing drugs or devices after a three-five year period of not doing so.

A pre-filed draft of SB 406 included the following language for an APRN to be eligible to execute a PAA:

- (c) requires the advanced practice nurse or physician assistant to be:*
- (1) practicing **with an active license in good standing in this state and without limitations or restrictions on such license in this or any other state;***
 - (2) **without current or permanent restrictions or exclusions from administering, providing or signing a prescription drug order by the board;***
 - (3) **without current or permanent restrictions, exclusions or prohibitions from administering, providing or signing a prescription drug order by any state or federal agency other than the board; and***

[Emphasis added]

This language is much more restrictive than the language in SB 406 as filed and passed. TNA acknowledges that the language being changed before SB 406 was filed bill lessens its value for establishing legislative intent. However, TNA believes it is still appropriate to consider the change in trying to determine how to interpret an APRN being in good standing for purposes of executing a PAA.

SUMMARY OF COMMENTS AND AGENCY RESPONSE.

General Comments

Comment: A commenter representing the Texas Medical Association (TMA) states that SB 406 reaffirms that the prescribing of drugs and devices is the practice of medicine, which is limited to those individuals who have been licensed to practice medicine by the Texas Medical Board. The commenter further states that physicians may delegate the prescribing and ordering of drugs or devices, but any such delegation must be appropriately supervised by a physician in accordance with the standard of care. SB 406 replaced an arbitrary system based on location and percentages with a system that is custom made for the individual physician and APRN based upon reasonableness and appropriateness. Further, the commenter states that, although SB 406 includes elements of a prescriptive authority agreement that must be addressed, the agreement may include more elements, more requirements, and more frequent meetings, as determined by the delegating and supervising physician.

Agency Response: The Board agrees with the commenter that an APRN has always been required to provide medical aspects of care under the delegated authority of a licensed physician. See the Occupations Code §157.001 and §157.005, which were not modified by SB 406.

Comment: A commenter representing the Texas Nurses Association (TNA) suggests moving Board Rules 221.14, 221.15, and 221.16 into Chapter 222 and re-wording the title of Chapter 222 to read: "Prescribing, Ordering or Providing Drugs or Devices by Advanced Practice Registered Nurses". The commenter states that SB 406 expanded the drugs an

APRN may prescribe or order under a prescriptive authority agreement to include controlled substances Schedule II in certain settings. The commenter states that this may provide certified nurse midwives and certified registered nurse anesthetists (CRNAs) an additional delegation mechanism for ordering controlled substances Schedule II in hospitals. The commenter believes it would promote a better understanding of the different delegation mechanisms if all the rules relating to physician delegation of prescribing, ordering, or providing drugs or devices to APRNs were set out in Chapter 222.

Agency Response: The Board declines to move the content of Board Rules 221.14, 221.15, and 221.16 into Chapter 222, as adopted, or to change the proposed title of Chapter 222. Re-organization of these two chapters is impractical at this time.

Comment: A commenter representing TNA notes that the rule does not set out an effective date. The commenter believes that the effective date of the adopted rule should be November 1, 2013, since the rule will implement the provisions of SB 406, which goes into effect November 1, 2013.

Agency Response: The Board disagrees. An agency rule cannot become effective before it is properly proposed and adopted under the Administrative Procedure Act. Although SB 406 will become effective on November 1, 2013, this statutory timeline does not have any effect upon the Board's adopted rule. The Board's rule will become effective 20 days after the Board submits its adoption to the Secretary of State's Office. Imposing an arbitrary effective date that pre-dates the adoption of the rules under the Administrative Procedure Act would be improper.

Comment: A commenter representing TNA believes it might be helpful if standardized terminology was identified and used throughout Rule 222, such as: (i) unless the context

clearly indicates otherwise, wherever the terms "prescribe", "prescription drug order", or "drug" appear, replace with "order or prescribe"; "prescription drug orders or medication orders"; and "drug or device", etc.; and (ii) unless the context clearly indicates otherwise, use "APRN with prescriptive authority" instead of varying terminology, such as "APRN with valid prescription authorization number", "APRN with full licensure and valid authorization number", and "APRN with full licensure".

Agency Response: The Board generally agrees with the comment and has made changes to the rule text as adopted to ensure that consistent terminology is used throughout the rule wherever possible.

Comment: A commenter representing TNA states that it is not clear that APRNs dispense, so the commenter is not sure why it is referred to in the proposed rule. If the term is referring to APRNs supplying drug samples, then the commenter believes it is better to state that explicitly.

Agency Response: The Board declines to make the suggested changes, as the Board believes the term "dispense" has a plain meaning understood by APRNs.

Comment: A commenter representing TNA believes there is redundancy in the proposed rule that could be eliminated to make the rule shorter and simpler. The commenter states that "protocol or other written authorization" is defined in §222.1 and §222.6. Since the term is used primarily in §222.6, the commenter suggests that may be the best place to define the term.

Agency Response: The Board declines to make the suggested change. The Board does not believe that defining the term in §222.1 makes the rule unnecessarily redundant or long. Rather, the Board believes that most readers would first refer to the definition section of the

rule (§222.1) when searching for the definition of the term. Further, although the term is discussed in detail in §222.6, this is not the only section of the rule that includes a reference to the term. As such, the Board believes that inclusion of the term in §222.1 is necessary.

Comment: A commenter representing TNA states that §222.10(b) is probably the more appropriate place to address requirements related to inspection and audits. In the proposed rule, it is addressed in both §222.4(f) and §222.10(b).

Agency Response: The Board declines to make the suggested change. While §222.4(f) and §222.10(b) both include references to inspection and audits, the two sections serve different purposes. Section 222.4 sets forth minimum standards of conduct related to an APRN prescribing or ordering drugs and devices, while §222.10 identifies conduct that may result in disciplinary action, including failing to meet the standards of conduct set out in §222.4. Further, because SB 406 specifically authorizes on site audits, the Board believes that it is important to specify an APRN's responsibility to cooperate during an audit, as well as providing adequate notice of the potential consequences of failing to do so.

Comment: A commenter representing TNA believes that, unless the context clearly indicates otherwise, any reference to "site" should be deleted from the rule. SB 406 eliminated the "site-based" model and "site" terminology is not used in SB 406.

Agency Response: The Board generally agrees and has eliminated the reference from §222.1(11) and §222.6 of the rule text as adopted. The remaining references to the term "site" in the rule text as adopted are necessary for context.

Comment: A commenter representing the Coalition for Nurses in Advanced Practice (CNAP) notes that the Texas Medical Board's proposed rules include the term "authorizing physician" to include a physician delegating prescriptive authority. For consistency, the

commenter recommends that the Board replace the term "collaborating physician" in §222.1(23) and §222.4(b)(10) with "authorizing physician" and the term "delegating physician" in §222.6 and §222.8(b)(2) and (3) with "authorizing physician".

Agency Response: The Board agrees that there should be consistency within its adopted rule. However, the Board declines to make the commenter's suggested change. Instead, the Board has determined that the term "delegating physician" is more consistent with the terminology of the Occupations Code Chapter 157, relating to Authority of Physician to Delegate Certain Medical Acts, and has replaced the term "collaborating physician" in adopted §222.1(23) and §222.4(b)(10) with the term "delegating physician".

Definitions

Comment: A commenter representing TNA believes that it is desirable for the definitions in Chapter 222 to track as closely as possible the definitions in SB 406, and when possible, the definitions used by the Texas Medical Board.

The commenter recommends that the definition of "advanced practice registered nurse" track the definition in SB 406 and the Nursing Practice Act §301.152. The commenter states that the proposed definition sets out criteria for how to qualify as an APRN instead of identifying the nurses to whom the rule applies. Although this type of definition may be appropriate in another rule, the commenter states that is unnecessary for this rule.

Further, the commenter states that the definition of durable medical equipment is unnecessary since the term "DME" is not ambiguous and is a term APRNs understand. DME is used in various Texas laws and rules relating to reimbursement for DMEs, and the commenter cannot find the term defined by any of these laws or rules. The commenter

believes that DME can be used as an undefined term.

The commenter recommends deleting the definition of "general hospital". The commenter states that the definition is unnecessary as the distinction between a general and special hospital is not relevant to an APRN prescribing or ordering drugs or devices.

The commenter also recommends deleting the definition of "special hospital", as the distinction between a general and special hospital is not relevant to an APRN prescribing or ordering drugs or devices.

The commenter recommends that the definition of "medication order" more closely track how SB 406 defines the term or how the Texas Medical Board defines the term in its proposed rules. The commenter states that the proposed definition does not capture adequately the aspect of a medication order being an order to a hospital pharmacist to dispense a medication.

With respect to the term "protocol or other written authorization", the commenter believes it would be desirable for the Board to review the Texas Medical Board's proposed definition to be sure the definitions are completely consistent. The definition of "protocol" in the Texas Medical Board's proposed rule states that a prescriptive authority agreement may reference a protocol. If the Board incorporates this language into its definitions, the commenter recommends that it describe the protocol as a "clinical protocol or guideline".

Finally, the commenter suggests adding the following definitions as necessary or appropriate: (i) APRN with prescriptive authority; (ii) prescription drug order, which may be needed to distinguish from "medication order"; and (iii) "authorizing physician", which would be the physician delegating the authority to an APRN to prescribe or order drugs or devices.

Agency Response: The Board agrees with many of the commenter’s suggestions. First, the Board agrees that the definitions in the rule as adopted should track the definitions contained in SB 406 verbatim. The Board has therefore amended the definitions of the terms “controlled substance”, “dangerous drug”, “device”, “medication order”, “non-prescription drug”, “physician group practice”, “prescribe or order a drug or device”, “prescription drug”, and “prescriptive authority agreement” in the rule as adopted to track the definitions set forth in SB 406 verbatim.

With respect to the definition of the term “advanced practice registered nurse”, the Board agrees with the comment and has amended the definition of this term in the rule as adopted to track the definition set forth in SB 406 verbatim.

With regard to the definitions of the terms “durable medical equipment”, “general hospital”, and “special hospital”, the Board agrees with the commenter and has deleted those definitions from the rule as adopted.

With respect to the definition of “protocol or other written authorization”, the Board has amended its definition of this term in the rule text as adopted to include additional language found in the Texas Medical Board's proposed definition of "protocols" to promote more consistency should the Texas Medical Board's proposed definition be adopted without changes.

The Board declines to make the commenter’s remaining suggested changes, as the Board believes that the amendments to the definitions in the rule as adopted provides sufficient clarity.

Comment: A commenter representing TMA opposes the definitions of "advanced health assessment", "advanced practice registered nurse", and "diagnosis and management

course". The commenter states that each of these proposed definitions implies that an APRN has the authority to make a medical diagnosis. The commenter opposes use of the word "diagnosis" in these proposed definitions because making a medical diagnosis is beyond the scope of nursing in Texas.

Further, the commenter states that it is inappropriate to define the term "advanced health assessment" in a way that would allow nurses to gain the knowledge and skill needed to perform an act which they are prohibited by law from performing, namely making diagnoses of health status.

The commenter also objects to the use of the term "diagnosis" in the definition of "advanced practice registered nurse". Regarding the definition of "diagnosis and management course", the commenter states that it is inappropriate to imply that a nurse can make a make a medical diagnosis and misleading to train nurses to perform an act that is prohibited by the Nursing Practice Act. The commenter goes on to state that diagnosis is the practice of medicine, and no one is allowed to practice medicine without a license from the Texas Medical Board. Further, the commenter states that the Legislature did not intend for nurses to diagnose. The Nursing Practice Act specifically excludes "diagnosis" from the nursing scope of practice. The commenter states that the Board does not have the authority to expand, by rule, a licensee's scope of practice beyond that authorized by the Legislature. The commenter urges the Board to remove the term "diagnose" from its proposed definitions.

The commenter also suggests changing the word "must" to "may" in the definition of "diagnosis and management course". The commenter states that the definition is misleading in that APRNs may only prescribe drugs or devices under the delegation and

supervision of a physician. If a physician does not delegate this act, or other acts which are the practice of medicine, then the APRN is not authorized to perform such acts. The commenter states that all references should be made to require delegation and supervision.

Agency Response: The Board disagrees that diagnosing is beyond the scope of an APRN who has been appropriately delegated the authority for medical aspects of care by a licensed physician. Under the Occupations Code §157.005, a person to whom a physician delegates the performance of a medical act is not considered to be practicing medicine unless the person acts with knowledge that the delegation is in violation of the authorizing statute/s. Further, under §157.001, a physician may delegate any medical act, within the scope of sound medical judgment, to a qualified and properly trained person acting under the physician's delegation, so long as the act can be properly and safely performed by the delegate, is performed in its customary manner, is not in violation of any other statute, and the delegate does not represent that he/she is authorized to practice medicine. Further, SB 406 amended the Occupations Code §301.002(2)(G) to specifically include the performance of an act delegated by a physician under the Occupations Code §§157.0512, 157.054, 157.058, or 157.059 in the scope of professional nursing. Because the law specifically contemplates the delegation of medical acts in such situations, an APRN who has been delegated the authority to perform such acts does not have to be licensed to practice medicine by the Texas Medical Board in order to do so.

Additionally, a physician cannot delegate a medical act to an APRN unless the APRN is qualified and properly trained. The Board agrees that an APRN cannot perform a medical act unless the act is delegated to the APRN by a licensed physician, in accordance with applicable law. The Board disagrees that its rules suggest otherwise and

it is not the Board's intention to do so. The Board's rules require APRNs to be educationally trained to assume responsibility for the assessment, diagnosis, and management of patient care, including the use and prescription of pharmacologic and non-pharmacologic interventions, in compliance with state law. The Board does not issue an APRN license to an individual unless the individual has shown that he/she has completed the requisite educational coursework and passed a national certification test, verifying that he/she is appropriately trained to perform delegated medical aspects of care. The Board must, therefore, set forth the minimum educational requirements that an individual must meet in order to be eligible for APRN licensure, including specifying the coursework that must be completed. Coursework in clinical decision making and aspects of medical diagnosis and medical management of diseases and conditions in the particular role and population focus area are an appropriate part of an APRN's training and education and must be if an APRN is to perform the delegated medical acts. If an APRN is not properly trained in these areas, the APRN cannot be an appropriate candidate for physician delegation because the APRN is not qualified to perform the delegated tasks. The Board's rule as adopted properly recognizes that delegation of medical aspects of care and the authority to prescribe or order drugs and devices to an APRN must conform to the requirements of SB 406, other relevant statutory requirements, and rules promulgated by the Texas Medical Board and the Board, as applicable. Therefore, with the exception of the definition of "advanced practice registered nurse", which has already been addressed in this response to comments, the Board declines to make the commenter's remaining suggested changes.

Comment: A commenter representing TMA states that, for the definition of "facility-based

practice site", the definition should be consistent with the Texas Medical Board's proposed rules and the intent of SB 406. The commenter suggests adding the following language to the proposed definition: "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".

The commenter also states that the definition of "prescribe or order a drug or device" is broader than the definition provided in SB 406, and the commenter recommends using the definition exactly as it appears in SB 406. Further, the commenter states that the Board's current rules contain a definition for "prescribing" and "signing a prescription drug order" that specify that an APRN must be designated to the Texas Medical Board by the delegating physician as a person delegated to sign a prescription. The commenter points out, however, that the proposed definition in the new chapter is silent regarding the requirement of delegation and such silence suggests a level of independence by stating that an APRN may be the one to determine the dangerous drug or controlled substances or devices that shall be used or administered. The commenter states that APRNs do not have independent practice to make such determinations. Rather, the determination will be delegated by a physician and will be made based on the specific drugs or devices that an APRN is authorized to prescribe pursuant to delegation and supervision.

The commenter further states that SB 406 replaced the term "carrying out or signing a prescription drug order" with "prescribing or ordering a drug or device". However, the commenter states that this change was not meant to be substantive. Therefore, the commenter states that the Board should not suggest a substantive change in its definition and suggests using the exact definition of "prescribing or ordering a drug or device" that

is used in SB 406.

The commenter also has concerns regarding the Board's use of the term "collaborating physician" in the Board's proposed definition of "protocols or other written authorization". The commenter states that the Legislature has shown that Texas does not authorize prescriptive authority to APRNs through a "collaboration model", but rather through delegation and supervision. The commenter states that the term "collaborating physician" is confusing and misleading. The commenter recommends that the Board replace the term "collaborating" with "delegating". The commenter supports a physician led team approach to patient care, but it must be clear that the team is physician led, not physician collaborated.

Finally, the commenter states that while the term "special hospital" is generally consistent with SB 406, it contains additional language that could be misleading. SB 406 references §241.003, Health and Safety Code. Although it appears that the Board has tracked the language from §241.003 in its proposed definition, the definition contains additional language pertaining to a medical staff in regular attendance "as required by the rules of the Department of State Health Services". The commenter states that this additional language is not in §241.003. Section 241.003 requires a medical staff in regular attendance, and does not refer to DSHS requirements. The requirement for a medical staff in regular attendance flows from statute, not from DSHS. There could also be other requirements that may apply, such as Joint Commission standards, in addition to requirements by DSHS. Thus, the commenter recommends removing the additional language from the proposed definition.

Agency Response: As explained previously in this response to comments, the Board has

determined that the term “prescribe or order a drug or device” should track the language of SB 406 verbatim and has amended the rule as adopted to incorporate this change. Further, as previously explained in this response to comments, the Board has determined that the term “special hospital” should be deleted from the rule as adopted. Also as previously explained in this response to comments, the Board has determined that references in the proposed rule to “collaborating physician” should be changed to “delegating physician” in the rule as adopted. Finally, with respect to the definition of “facility based practice”, the Board agrees with the commenter and, for consistency with the proposed definition of the Texas Medical Board, has amended the definition of “facility based practice” to include the additional language suggested by the commenter.

§222.2

Comment: A commenter representing TMA opposes the implication in proposed §222.2(a)(2) that a nurse is authorized to make a medical diagnosis. The commenter states that professional nursing does not include acts of medical diagnosis. The commenter urges the Board to remove reference to diagnosis from this section.

Agency Response: The Board declines to make this change. As previously explained in this response to comments, pursuant to the Occupations Code §§157.001, 157.005, and 301.002(2)(G), an APRN who has been properly delegated a medical act by a licensed physician may carry out that act, provided that all statutory and regulatory requirements are met.

§222.3

Comments: A commenter representing TNA believes that §222.3 should clarify that the three hours of continuing education in ordering or prescribing controlled substances is in

addition to any continuing education required to maintain the APRN's registered nurse license. Further, the commenter notes that the proposed rule does not set out a start date for when APRNs must show compliance with the new continuing education requirement and states that there should be at least one year lead time to allow for the continuing education offering to be developed and for APRNs to meet the new requirement.

A commenter representing TMA supports the additional continuing educational requirements of this section and states that the required number of hours could be higher. The commenter states that APRNs with prescriptive authority should be educated regularly regarding the potential for controlled substance abuse and diversion. Opioid addiction is a national epidemic and all health care providers involved in the prescribing, administering, or dispensing of controlled substances should be well apprised of the issues involved, including appropriate safeguards, regulations, and standards of care.

A commenter representing CNAP supports requiring three additional hours of continuing education relating to prescribing controlled substances. The commenter believes the additional continuing education is consistent with discussions among legislators during the 83rd Texas Legislature as they debated and passed SB 406. The commenter believes the additional hours of continuing education helps APRNs continue to treat patients with the utmost care and safety. However, the commenter requests that the implementation of the new requirements become effective no earlier than January 1, 2015 to give APRNs time to identify and complete the coursework necessary to comply with the new requirements. Further, the commenter suggests that the Board clarify that the additional three hours of continuing education relating to prescribing controlled substances is in addition to the continuing education required only under §216.3(c)(1) and (2). The

commenter provides suggested language as follows:

(b) the APRN seeking to maintain prescriptive authority shall attest, on forms provided by the Board, to completing at least five contact hours of continuing education in pharmacotherapeutics within the preceding biennium, as required in §216.3(c)(3). After January 1, 2015, those APRNs seeking to maintain prescriptive authority who order or prescribe controlled substances shall attest, on forms provided by the Board, to completing at least three additional contact hours of continuing education related to prescribing controlled substances within the preceding biennium, as required in §216.3(c)(3).

(c) The continuing education requirements in subsection (b) of this section shall be in addition to continuing education required under §216.3(c)(1) and (2) of this title (relating to Continuing Competency).

Agency Response: The Board agrees that requiring additional hours of continuing education is in the best interests of patients and the public and that APRNs who prescribe controlled substances should be educated regularly regarding the potential for controlled substance abuse and diversion and appropriate safeguards, regulations, and standards of care. Further, the Board agrees that the rule as adopted should establish a compliance date and has amended subsection (b) of the rule text as adopted in this regard. Further, the Board has provided additional language in subsection (c) of the rule text as adopted to clarify the continuing education requirements applicable to APRNs.

§222.4

Comment: A commenter representing CNAP states that the rule should be amended to reflect that APRNs must comply with the chart review requirements in the prescriptive authority agreement or the requirements in the facility-based written protocols or other

written authorization, but not both. The commenter provides the following suggested language:

(a) The APRN with a valid prescription authorization number shall:

(1) order or prescribe only those drugs or devices that are:

(A) authorized by a prescriptive authority agreement or, if practicing in a facility based practice, authorized by either a prescriptive authority agreement or protocols or other written authorization; and

(B) ordered or prescribed for patient populations within the accepted scope of professional practice for the APRN's license; and

(2) comply with the requirements for chart reviews specified in the prescriptive authority agreement and periodic face to face meetings set forth in this chapter; or

(3) comply with the requirements set forth in protocols or other written authorization if ordering or prescribing drugs or devices under facility-based protocols or other written authorization.

Agency Response: The Board agrees with the commenter and has made the suggested change in the rule text as adopted.

Comment: A commenter representing TMA states that the requirements related to periodic face to face meetings are to be set forth in the prescriptive authority agreement and not the Board's rules. Further, the commenter states that the rules should be written to reflect that the elements of the prescriptive authority agreement are at a minimum. Section 157.0512(g) states that the prescriptive authority agreement may include other provisions agreed to by the physician and APRN or physician assistant. Therefore, it is the

prescriptive authority agreement, and not the Board's rules and not statute, which provide the requirements for periodic face to face meetings. The commenter suggests replacing "set forth in this chapter" with "set forth in the prescriptive authority agreement".

The commenter is also concerned about the reference to "collaborating physician" in §222.4(b)(10). The commenter states that Texas does not authorize prescriptive authority for an APRN through collaboration. The prescribing of drugs or devices by an APRN or PA may only be accomplished through the delegation and supervision of a physician. The commenter therefore urges the Board to remove references to "collaborating physician" from its proposed rules and, because it is inaccurate and misleading, replace such terminology with "delegating physician".

Agency Response: The Board agrees that the minimum requirements for a prescriptive authority agreement are set forth in SB 406. The Board further agrees that a prescriptive authority agreement may contain additional or more prescriptive elements than specified by SB 406, as determined and agreed to by the parties to the agreement. As such, the Board agrees with the commenter and has amended §222.4(a)(2) as adopted accordingly. Further, as has been previously explained in this response to comments, the Board has amended the term "collaborating physician" to "delegating physician" throughout the rule text as adopted.

§222.5(a)

Comments: A commenter representing TNA suggests rewording this subsection so that it does not imply that a prescriptive authority agreement is the only delegation mechanism that can be used to authorize an APRN to prescribe or order drugs or devices. In addition to a prescriptive authority agreement, the commenter states that a protocol may also be

used as the delegation mechanism in a facility-based practice and Medical Practice Act §157.058 is an additional delegation available to CRNAs.

A commenter representing the Texas Association of Nurse Anesthetists (TANA) recommends that the word "the" be changed to the word "a" to indicate that a prescriptive authority agreement is a mechanism by which a CRNA may be delegated the authority to order or prescribe drugs or devices by a physician. The commenter states, however, that SB 406 did not alter the provisions of the Occupations Code §157.058 and a CRNA may continue to obtain delegated authority for the ordering of the drugs and devices necessary for the CRNA to administer an anesthetic or an anesthesia-related service ordered by a physician pursuant to §157.058.

A commenter representing CNAP also recommends that the word "the" be changed to the word "a" to reflect the intent of SB 406 that APRNs in facility-based practices can also use protocols or other written authorizations in lieu of a prescriptive authority agreement. The commenter states that the lack of changes in the Occupations Code §157.058 and the minimal changes to §157.054 in SB 406 were intended to ensure a mechanism for CRNAs and other hospital-based APRN practices to continue as they currently practice.

Agency Response: The Board agrees with the comments and has amended the rule text as adopted accordingly.

§222.5(b)

Comments: A commenter representing TNA notes that the proposed definition of "good standing" would preclude an APRN from executing a prescriptive authority agreement if there was any current adverse action against the APRN's license or authorization or even

if there is a pending investigation. The commenter does not believe this interpretation is the correct interpretation of Medical Practice Act §157.0512(b)(2)(A) or one supported by the rules of statutory construction. Further, the commenter does not believe it is good public policy to place restrictions on a nurse's practice based on the opening of an investigation or on the filing of formal charges. The commenter states that the Nursing Practice Act §301.455 gives the Board the authority to immediately suspend or restrict a nurse's license if it believes the nurse's practice poses an imminent threat to the public welfare. Adoption of a rule placing restrictions on a nurse's license on the basis of a pending investigation or formal charges would be setting a bad precedent. The commenter suggests that the Board define "good standing" as determined only on the basis of a final disciplinary action against an APRN and not on the basis of opening of an investigation or filing of formal charges and so that not every adverse action, regardless of severity, against an APRN's license or authorization categorically precludes an APRN from executing a prescriptive authority agreement. The commenter's suggested language also includes a mechanism for APRNs with adverse actions pending on November 1, 2013, to be able to execute a prescriptive authority agreement. The commenter also recognizes that there may be other mechanisms that would accomplish the desired result. The commenter proposes the following language:

(b) An APRN with prescriptive authority and a physician are eligible to enter into or be parties to a prescriptive authority agreement only if the APRN:

(1) holds an active license to practice in this state and the APRN is in good standing. An APRN is in good standing if the APRN's nursing license(s) or authorization(s) is not encumbered, or if encumbered, the APRN is permitted by Board order to be a party

to a prescriptive authority agreement. APRNs with a license or authorization encumbered as of November 1, 2013, shall be considered in good standing if in compliance with any restriction or condition of probation imposed on the license or authorization.

A commenter representing CNAP recommends striking the definition of "good standing" as proposed and using its recommended definition. The commenter states that the definition as proposed would prohibit an APRN from being a party to a prescriptive authority agreement if the Board opened an investigation involving any APRN. This, the commenter states, would in effect prohibit the APRN from prescribing or ordering drugs except in facility based practices. The commenter states that, since most complaints do not result in a finding that the APRN violated the Nursing Practice Act, and the majority of complaints do not relate to the APRN's competence in prescribing, it would be inappropriate to prohibit an APRN from prescribing before the Board actually took any disciplinary action against the APRN and determined that the APRN was not competent to prescribe or order drugs and medical devices. The commenter recommends the following language:

(b) An APRN with prescriptive authority and a physician are eligible to enter into or be parties to a prescriptive authority agreement only if the APRN:

(1) holds an active license to practice in this state that is in good standing. For purposes of this chapter, "good standing" means that the advanced practice registered nurse's license has not been suspended and the Board of Nursing has not taken disciplinary action that prohibits the nurse from executing a prescriptive authority agreement.

Agency Response: The Board generally agrees with the commenters that the definition of

“good standing” in §222.5(b) as proposed is too limiting in nature. However, the Board declines to adopt the commenters’ suggested language. The Board believes that an APRN’s eligibility to enter into a prescriptive authority agreement should be based upon the licensure status of the APRN and whether the APRN’s license and/or prescriptive authorization number is encumbered by a disciplinary action. The Board has therefore amended the rule text as adopted accordingly.

§222.5(c)

Comments: A commenter representing CNAP recommends that the wording of the paragraph be re-ordered to more closely reflect the statute so the reader knows immediately that designating an alternate physician or physicians is not required. The commenter proposes the following language:

(8) if an alternate physician arrangement is to be utilized, designate one or more alternate physicians who may participate in the execution of the prescriptive authority agreement in accordance with the rules of the Texas Medical Board; and

A commenter representing TMA opposes §222.5(c)(8) as written because it inaccurately states that a prescriptive authority agreement may designate one or more alternate physicians who may participate in the execution of the prescriptive authority agreement. The commenter states that §222.5(c)(8) is inaccurate in that it allows an alternate physician to execute the prescriptive authority agreement, which SB 406 does not permit; because it does not specify that alternate supervision is allowed only in a physician group practice; and because it does not provide that the supervision is to be on a temporary basis. The commenter suggests that the Board track the language of the Occupations Code §157.0512(e)(8) directly, such that the specifics that the statute provides

are clearly provided in the rule.

Agency Response: The Board agrees that the rule text should track the language of SB 406 verbatim, and has amended the rule text as adopted accordingly.

§222.5(d)

Comments: A commenter representing TMA has concerns about §222.5(d)(2)(B). The commenter states that the paragraph does not clearly reflect that the minimums for periodic face to face meetings can be modified based *only* on previous involvement of prescriptive authority with the same physician who is executing the prescriptive authority agreement. The commenter points out that the Texas Medical Board's proposed rules require the same physician to be involved in the previous delegation and TMA believes this is the correct interpretation of SB 406. In order to accurately reflect the intent of SB 406, and to be consistent with the Texas Medical Board's interpretation, the commenter suggests the following language: "If during the seven years preceding the date the agreement is executed, the advanced practice registered nurse was supervised for at least five years in a practice that included the exercise of prescriptive authority with required physician supervision by the physician with whom the prescriptive authority agreement is entered..."

Agency Response: The Board declines to make the commenter's suggested change, as the Board believes its proposed language is generally consistent with the language of SB 406. However, to the extent that the proposed rule text is not exactly the same as the language of SB 406, the Board has made minor changes in the rule text as adopted to ensure that the rule text as adopted tracks the language of SB 406 verbatim.

Comment: A commenter representing TNA suggests adding a new subdivision to the proposed section to emphasize that SB 406 authorizes credit for time the delegating

physician and APRN practiced together (with APRN authorized to prescribe) prior to November 1, 2013. The commenter states that not addressing the credit in the rule may result in some APRNs not realizing the credit is available. The commenter suggests the following language:

(C) If during any period of time prior to November 1, 2013, the APRN practiced under the delegated prescriptive authority of the physician signing the prescriptive authority agreement, that period of time shall be included in calculating the third anniversary under Subdivision (A)(i) or the first anniversary under Subdivision (B)(i).

Agency Response: The Board acknowledges that the rule text as proposed does not include all of the language of SB 406 that may affect the calculation of time under §222.5. As such, the Board has amended the text of the rule as adopted to track the language of SB 406 verbatim, including the bill's provisions regarding the calculation of the amount of time, in new subsection (m).

§222.5(e)

Comment: A commenter representing TMA supports §222.5(e), which states that a prescriptive authority agreement may include other provisions. The commenter reiterates that the elements of the agreement enumerated in SB 406 are only minimums and the requirements of delegation and supervision will be tailored to the health care providers involved, in accordance with the standard of care.

Agency Response: The Board agrees that SB 406 prescribes the minimum requirements that must be included in a prescriptive authority agreement and that the prescriptive authority agreement may include additional or more restrictive provisions agreed to by the parties to the agreement consistent with the standard of care.

§222.5(f)

Comments: A commenter representing TMA states that §222.5(f) should be clarified to reflect that an alternate physician, if any, must be designated in the prescriptive authority agreement. The commenter suggests adding "in the prescriptive authority agreement" after "has been designated" and before "to conduct and document" in subsection (f).

A commenter representing CNAP states that the rule appears to limit the participation of alternate physicians in quality assurance meetings to those in physician group practices. The commenter states that, although §157.0512(h) is limited to a physician group practice, §157.0512(8) is more broadly written. The commenter recommends the following language:

(f) The APRN shall participate in quality assurance meetings with an alternate physician if an alternate physician has been designated in the prescriptive authority agreement.

Agency Response: The Board agrees with the commenters and has made changes to the rule text as adopted. The Board notes that, when read together, the Occupations Code §157.0512(e)(8) and (h) require that an alternate supervising physician, if any, be designated in the prescriptive authority agreement. Further, the Board agrees that the provisions of SB 406 do not limit the designation of an alternate supervising physician to a physician group practice only. As such, the Board has removed the limiting language from the rule text as adopted.

§222.5(i)

Comment: With respect to §222.5(i), a commenter representing TMA points out that §157.0512(k) states that a party to an agreement may not by contract waive, void, or nullify

any provision of §157.0512 or §157.0513. The commenter suggests adding "or §157.012 or §157.0513, Occupations Code" to the proposed rule to make clear that a party may not waive, void, or nullify any provision of the rules or the statutory provisions.

Agency Response: Although the Board does not believe that the suggested language is necessary since the statutory provisions of SB 406 clearly speak for themselves, the Board has nonetheless included a reference to §157.0512(k) in the rule text as adopted for additional clarity.

§222.5 (additional subsection)

Comment: A commenter representing TANA recommends adding a new subsection to clarify that SB 406 does not require a CRNA to practice pursuant to a prescriptive authority agreement, but that CRNAs may continue to order drugs and devices necessary to administer anesthesia and anesthesia-related services pursuant to the Occupations Code §157.058. The commenter recommends the following language: "A nurse anesthetist to whom a physician has delegated the ordering of drugs and devices necessary for the nurse anesthetist to administer anesthesia or anesthesia-related services, including pre-operative, post-operative, and consultative services, pursuant to Section 157.058 of the Texas Occupations Code is not required to obtain a prescriptive authority agreement for the ordering of prescription or non-prescription drugs, dangerous drugs, or controlled substances."

Agency Response: The Board agrees with the commenter that SB 406 does not require a CRNA to practice pursuant to a prescriptive authority agreement and that a CRNA may continue to order drugs and devices necessary to administer anesthesia and anesthesia-related services under physician delegation, as provided for in the Occupations Code

§157.058. Because SB 406 did not amend §157.058, the Board does not believe it is necessary to include the suggested language in the rule as adopted.

§222.6

Comments: A commenter representing CNAP recommends deleting "sites" in the title of the section and the text of subsection (a), as that definition has been removed from the statute and the rest of the proposed rules. The commenter further recommends that "this section" be deleted from §222.6(a)(1) since it is the APRN who must meet the requirements, not the document. The commenter also recommends modifying the formatting of the paragraph if it is the Board's intent that any written authorization used for prescriptive authority is in accordance with facility policy and reviewed annually. The commenter proposes the following language:

(a) When ordering or prescribing a drug or device at a facility-based practice, the APRN with prescriptive authority shall:

(1) maintain either a prescriptive authority agreement or protocols or other written authorization;

(A) developed in accordance with facility medical staff policies; and

(B) reviewed with the appropriate medical staff at least annually;

A commenter representing TMA points out a presumed typographical error, in that there is a reference to meeting the prescriptive authority agreement requirements "of this section". However, the prescriptive authority agreement requirements are located in proposed section §222.5 and not §222.6. The commenter recommends making reference to §222.5 instead.

A commenter representing TNA suggests amending the section's title by removing

"site" since SB 406 eliminated the "site-based" model and "site" terminology is not used in SB 406. The commenter further states that SB 406 does not explicitly address the issue of prescriptive authority agreements in facility based practices. However, §157.0512 does not limit the practices where an agreement can be used. Section 157.054 neither explicitly permits nor precludes the use of a prescriptive authority agreement at a facility based practice. However, §157.054 authorizes delegation of prescribing and ordering at a facility based practice only if certain requirements are met. The commenter believes that the most plausible interpretation of SB 406 is that a prescriptive authority agreement may be used as a delegation mechanism at a facility based practice and, if used, must comply with the requirements of both §157.0512 (relating to prescriptive authority agreements) and §157.054 (relating to facility based practices). If this is the correct interpretation of SB 406, the commenter believes the Board's rules should explicitly state that if a prescriptive authority agreement is used at a facility based practice, it must meet the requirements of both §222.5 and §222.6.

Agency Response: The Board agrees that the term "site" should be removed from the title of the section, as well as from the section itself, and has made these suggested changes in the rule text as adopted. The Board further agrees that there is a typographical error in §222.6(a)(1) as pointed out by the commenter and has changed the rule text as adopted to appropriately reference §222.5 instead. Regarding the remainder of the comments, the Board has amended the rule text to better clarify the requirements that apply when prescriptive authority agreements are utilized in facility based practices and when protocols and other written authorization are utilized in facility based practices. Additionally, the Board has determined that the language of the Occupations Code §157.054 (b-1) should

be included in the rule text as adopted to provide further clarity regarding the use of prescriptive authority agreements in facility based practices.

§222.7

Comments: A commenter representing CNAP states that the last sentence of the section should be deleted because it deals with prescribing controlled substances and appears inappropriate in this section. The language to be deleted is: "APRNs with full licensure and valid prescription authorization numbers are not eligible to order or prescribe controlled substances unless they meet the applicable requirements of this rule".

Comment: A commenter representing TMA states that this section is concerning in that it does not reference the delegation and supervision by a physician to an APRN. Rather, the commenter points out that the rule states that APRNs are eligible to order or prescribe non-prescription drugs, dangerous drugs, and devices. Further, it also states that APRNs are not eligible to order or prescribe controlled substances unless they meet the applicable requirements of the rule. The commenter suggests that the rule should reference the requirement for delegation and supervision, prior to an eligible APRN being able to exercise prescriptive authority. Further, the commenter points out that the last sentence of the proposed rule references the requirements "of this rule", but it is the requirements of §222.8 that should be met pertaining to controlled substances. The commenter recommends that §222.8 be referenced in the proposed rule and that the requirement of physician delegation and supervision be referenced as well.

Agency Response: As previously explained in this response to comments, the Board does not believe the proposed rules authorize an APRN to order or prescribe drugs or devices without appropriate delegation from a licensed physician. However, the Board agrees that

the section should be clarified in general. The purpose of the section is to recognize that an APRN may not wish to obtain authority to prescribe or order controlled substances. Instead, the APRN may only wish to obtain authority to prescribe or order non-prescription drugs, dangerous drugs, and devices. Therefore, the section is intended to set forth the requirements that apply to an APRN who wishes to obtain authority to prescribe or order non-prescription drugs, dangerous drugs, and devices only and to clarify that an APRN who wishes to also prescribe or order controlled substances must meet the requirements of §222.8 in order to be eligible to do so. The Board has amended the rule text as adopted to clarify these issues.

§222.8

Comments: A commenter representing TNA states that the requirement that an APRN comply with DPS and DEA requirements are set out in §222.8(a) and (d).

A commenter representing CNAP states that (a) and (d) are redundant and (d) should be deleted in favor of (a).

Agency Response: The Board agrees with the comments and has deleted subsection (d) in the rule text as adopted.

§222.10

Comment: A commenter representing CNAP states that the rule contemplates the Board notifying the Texas Medical Board and the Texas Physician Assistant Board when an APRN becomes the subject of an investigation regarding the delegation of prescriptive authority. The commenter suggests that a new subsection (d) be added to require notification of the Texas Physician Assistant Board only when a physician assistant is a party to a prescriptive authority agreement involving an APRN subject to investigation. If

there is not a physician assistant included in the agreement, the commenter states that notification by the Board appears to be unnecessary and of no public benefit. The commenter suggests the following language:

(c) The Board shall immediately notify the Texas Medical Board and the Texas Physician Assistant Board:

(1) when an APRN licensed by the Board becomes the subject of an investigation involving the delegation and supervision of prescriptive authority; and

(2) upon the final disposition of an investigation an APRN licensed by the Board and the delegation and supervision of prescriptive authority.

(d) If no physician assistant is party to the prescriptive authority agreement of an advanced practice registered nurse, the Board is not required to notify the Texas Physician Assistant Board.

Agency Response: The Board declines to make the suggested change. SB 406 requires the Board to immediately notify both the Texas Medical Board and the Texas Physician Assistant Board when a license holder becomes the subject of an investigation, as well as when there is a final disposition of the investigation. The Board believes its proposed requirements are more consistent with the provisions of SB 406 than the suggested revisions of the commenter.

§222.10(f)

Comment: A commenter representing CNAP states that this section references "sign prescription drug orders", which should be changed to "order or prescribe" for consistency with SB 406. The commenter suggests the following language:

(f) The practice of the APRN approved by the Board to order and prescribe is

subject to monitoring by the Board on a periodic basis.

Agency Response: The Board agrees with the comment and has amended the rule text as adopted to reflect this suggested change.

Comment: A commenter representing TNA recommends adding a new §222.10 whose content would include that of current Rule 221.16, related to CRNAs ordering anesthesia-related drugs and devices. The commenter states that, prior to the passage of SB 406, Medical Practice Act §157.058 addressed the delegation mechanism for CRNAs to order controlled substances Schedule II anesthesia-related drugs. SB 406 provided potential additional mechanisms by permitting APRNs to prescribe schedule II controlled substances for hospital inpatients and hospital emergency room patients under protocols and prescriptive authority agreements. The commenter feels there may now be confusion about what delegation mechanism can be used to authorize CRNAs to order anesthesia-related drugs and services. The commenter believes that adding the new language will make explicit that the delegation mechanism allowed by Medical Practice Act §157.058 remains an option available to CRNAs. The commenter suggests using the current text from §221.15, and adding "notwithstanding any other section of this chapter, " to the beginning of the section.

Agency Response: The Board declines to make the change. As previously explained in this response to comments, the Board agrees that SB 406 does not require a CRNA to practice pursuant to a prescriptive authority agreement and that a CRNA may continue to order drugs and devices necessary to administer anesthesia and anesthesia-related services under physician delegation, as provided for in the Occupations Code §157.058. Because SB 406 did not amend §157.058, the Board does not believe it is necessary to

include the suggested language in the rule as adopted.

Amended Text In Response to Comments (changes in yellow highlight)

§222.1. Definitions. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

(1) Advanced health assessment--A course that offers content supported by related clinical experience such that students gain the knowledge and skills needed to perform comprehensive assessments to acquire data, make diagnoses of health status, and formulate effective clinical management plans. Content must include assessment of all human systems, advanced assessment techniques, concepts, and approaches.

(2) Advanced Pharmacotherapeutics--A course that offers advanced content in pharmacokinetics, pharmacodynamics, pharmacotherapeutics of all broad categories of agents, and the application of drug therapy to the treatment of disease and/or the promotion of health.

(3) Advanced Physiology and Pathophysiology--A dedicated, comprehensive, system-focused pathology course(s) that provides students with the knowledge and skills to analyze the relationship between normal physiology and pathological phenomena produced by altered states across the life span.

(4) Advanced practice registered nurse (APRN)--As defined by §301.152, Occupations Code. The term includes an advanced nurse practitioner and advanced practice nurse.

(5) Board--The Texas Board of Nursing.

(6) Controlled Substance--As defined by §481.002, Health and Safety Code.

(7) Dangerous Drug--As defined by §483.001, Health and Safety Code.

(8) Device--As defined by §551.003, Occupations Code, and includes durable medical equipment.

(9) Diagnosis and management course--A course offering both didactic and clinical content in clinical decision-making and aspects of medical diagnosis and medical management of diseases and conditions. Supervised clinical practice must include the opportunity to provide pharmacological and non-pharmacological management of diseases and conditions considered within the scope of practice of the APRN's population focus area and role.

Definition of *durable medical equipment* removed

(10) Facility-based practice--A hospital, as defined by §157.051(6), Occupations Code, 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.

Definition of *general hospital* removed

(11) Health professional shortage area--

(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 non-profit private medical facility or other facility that the Secretary of Health and Human Services determines has a health profession shortage as described by 42 U.S.C. §254e(a)(1).

(14) 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 a state; or

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

(B) has an organized medical staff.

(15) Medication order--As defined by §551.003, Occupations Code and §481.002, Health and Safety Code.

(16) Non-prescription drug--As defined by §551.003, Occupations Code.

(17) 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 non-profit health organization certified by the Texas Medical Board under §162.001(b), Occupations Code, that complies with the requirements of Chapter 162.

(18) Population focus area--The section of the population with which the APRN has been licensed to practice by the Board.

(19) Practice serving a medically under-served population--

(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(1)(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 APRN or physician assistant on or before March 1, 2013, based on the practice qualifying as a site serving a medically under-served population.

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

(21) Prescription drug--As defined by §551.003, Occupations Code.

(22) Prescriptive authority agreement--An agreement entered into by a physician and an APRN or physician assistant through which the physician delegates to the APRN or physician assistant the act of prescribing or ordering a drug or device.

(23) Protocols or other written authorization--Written authorization to provide medical aspects of patient care that are agreed upon and signed by the APRN and delegating physician, reviewed and signed at least annually, and maintained in the practice setting of the APRN. The term "protocols or other written authorization" is separate and distinct from a prescriptive authority agreement. However, a prescriptive authority agreement may reference or include the terms of a protocol or other written authorization. Protocols or other written authorization shall be defined to promote the exercise of professional judgment by the APRN commensurate with his/her education and experience. Such protocols or other written authorization need not describe the exact steps that the APRN must take with respect to each specific condition, disease, or symptom and may state types or categories of drugs or devices that may be prescribed or ordered rather than just list specific drugs or devices.

(24) Shall and must--Mandatory requirements.

(25) Should--A recommendation.

Definition of *special hospital* removed

§222.2. Approval for Prescriptive Authority.

(a) To be issued a prescription authorization number to prescribe or order a drug or device, a registered nurse (RN) shall:

(1) have full licensure from the Board to practice as an APRN. RNs with Interim Approval to practice as APRNs are not eligible for prescriptive authority; and

(2) file a complete application for Prescriptive Authority and submit such evidence as required by the Board to verify successful completion of graduate level courses in advanced pharmacotherapeutics, advanced pathophysiology, advanced health assessment, and diagnosis and management of diseases and conditions within the role and population focus area.

(A) Nurse Practitioners, Nurse-Midwives, and Nurse Anesthetists will be considered to have met the course requirements of this section on the basis of courses completed in the advanced practice nursing educational program.

(B) Clinical Nurse Specialists shall submit documentation of successful completion of separate, dedicated, graduate level courses in the content areas described in paragraph (2) of this subsection. These courses shall be academic courses with a minimum of 45 clock hours per course from a nursing program accredited by an organization recognized by the Board.

(C) Clinical Nurse Specialists who were previously approved by the

Board as APRNs by petition on the basis of completion of a non-nursing master's degree shall not be eligible for prescriptive authority.

(b) APRNs applying for prescriptive authority on the basis of endorsement of advanced practice licensure and prescriptive authority issued in another state must provide evidence that all education requirements for prescriptive authority in this state have been met.

§222.3. Renewal of Prescriptive Authority.

(a) The APRN shall renew the privilege to sign prescription drug orders and medication orders in conjunction with the RN and advanced practice license renewal application.

(b) The APRN seeking to maintain prescriptive authority shall attest, on forms provided by the Board, to completing at least five contact hours of continuing education in pharmacotherapeutics within the preceding biennium. In every licensure cycle after January 1, 2015, those APRNs seeking to maintain prescriptive authority who order or prescribe controlled substances shall attest, on forms provided by the Board, to completing at least three additional contact hours of continuing education related to prescribing controlled substances within the preceding biennium.

(c) The continuing education requirements in subsection (b) of this section shall be in addition to continuing education required under Chapter 216 of this title (relating to Continuing Competency) for APRNs.

§222.4. Minimum Standards for Prescribing or Ordering Drugs and Devices.

(a) The APRN with full licensure and a valid prescription authorization number shall:

(1) order or prescribe only those drugs or devices that are:

(A) authorized by a prescriptive authority agreement or, if practicing in a facility-based practice, authorized by either a prescriptive authority agreement or protocols or other written authorization; and

(B) ordered or prescribed for patient populations within the accepted scope of professional practice for the APRN's license; and

(2) comply with the requirements for chart reviews specified in the prescriptive authority agreement and periodic face to face meetings set forth in the prescriptive authority agreement; or

(3) comply with the requirements set forth in protocols or other written authorization if ordering or prescribing drugs or devices under facility-based protocols or other written authorization.

(b) Prescription Information. The format and essential elements of a prescription drug order shall comply with the requirements of the Texas State Board of Pharmacy. The following information must be provided on each prescription:

(1) the patient's name and address;

(2) the name, strength, and quantity of the drug to be dispensed;

(3) directions to the patient regarding taking of the drug and the dosage;

(4) the intended use of the drug, if appropriate;

(5) the name, address, and telephone number of the physician with whom the APRN has a prescriptive authority agreement or facility-based protocols or other written authorization;

(6) address and telephone number of the site at which the prescription drug order was issued;

(7) the date of issuance;

(8) the number of refills permitted;

(9) the name, prescription authorization number, and original signature of the APRN who authorized the prescription drug order; and

(10) the United States Drug Enforcement Administration numbers of the APRN and the **delegating** physician, if the prescription drug order is for a controlled substance.

(c) Generic Substitution. The APRN shall authorize or prevent generic substitution on a prescription in compliance with the current rules of the Texas State Board of Pharmacy relating to generic substitution.

(d) An APRN may order or prescribe medications for sexually transmitted diseases for partners of an established patient, if the APRN assesses the patient and determines that the patient may have been infected with a sexually transmitted disease. Nothing in this subsection shall be construed to require the APRN to issue prescriptions for partners of patients.

(e) APRNs may order or prescribe only those medications that are FDA approved unless done through protocol registration in a United States Institutional Review Board or Expanded Access authorized clinical trial. "Off label" use, or prescription of FDA-approved medications for uses other than that indicated by the FDA, is permitted when such practices are:

(1) within the current standard of care for treatment of the disease or condition; and

(2) supported by evidence-based research.

(f) The APRN with full licensure and a valid prescriptive authorization number shall cooperate with representatives of the Board and the Texas Medical Board during an inspection and audit relating to the operation and implementation of a prescriptive authority agreement.

§222.5. Prescriptive Authority Agreement.

(a) The prescriptive authority agreement is a mechanism by which an APRN is delegated the authority to order or prescribe drugs or devices by a physician.

(b) An APRN with full licensure and a valid prescriptive authorization number and a physician are eligible to enter into or be parties to a prescriptive authority agreement only if the APRN:

(1) holds an active license to practice in this state that is in good standing.

For purposes of this chapter, an APRN is in good standing if the APRN's license and prescriptive authorization number are not encumbered by a disciplinary action;

(2) is not currently prohibited by the Board from executing a prescriptive authority agreement; and

(3) before executing the prescriptive authority agreement, the APRN and the physician disclose to the other prospective party to the agreement any prior disciplinary action by the applicable licensing board.

(c) A 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 either:
 - (A) the types or categories of drugs or devices that may be ordered or prescribed; or
 - (B) the types of categories of drugs or devices that may not be ordered or 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 APRN and the physician 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 Chapter 157, Subchapter B, Occupations Code; and
 - (B) participate in the prescriptive authority quality assurance and improvement plan meetings required under §157.0512, Occupations Code;

(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 APRN and physician; and

(B) periodic face to face meetings between the APRN and the physician at a location agreed upon by both providers.

(d) The periodic face to face meetings described by subsection (c)(9)(B) of this section must:

(1) include:

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

(B) discussion of patient care improvement; and

(2) be documented and occur:

(A) except as provided by subparagraph (B) of this paragraph:

(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 video conferencing technology or the internet; or

(B) if during the seven years preceding the date the agreement is executed, the APRN for at least five years was in a practice that included the exercise of prescriptive authority with required physician supervision:

(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 video conferencing technology or the internet.

(e) Although a prescriptive authority agreement must include the information specified by this section, the agreement may include other provisions agreed to by the APRN and physician, including provisions that were previously contained in protocols or other written authorization.

(f) The APRN shall participate in quality assurance meetings with an alternate physician if the alternate physician has been designated in the prescriptive authority agreement to conduct and document the meeting.

(g) The prescriptive authority agreement is not required to describe the exact steps that an APRN must take with respect to each specific condition, disease, or symptom.

(h) An APRN 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.

(i) A party to the prescriptive authority agreement may not by contract waive, void, or nullify any provision of this rule or §157.012 or §157.0513, Occupations Code.

(j) 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 respective licensing board, the individual shall immediately notify the other party to the prescriptive authority agreement.

(k) 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 shall be made available to the Board, the Texas Medical Board, or the Texas Physician Assistant Board not later than the third business day after the date of receipt of the request from the respective licensing board.

(l) The prescriptive authority agreement should promote the exercise of professional judgment by the APRN commensurate with the APRN's education and experience and the relationship between the APRN and the physician.

(m) The calculation under Chapter 157, Occupations Code, of the amount of time an APRN has practiced under the delegated prescriptive authority of a physician under a prescriptive authority agreement shall include the amount of time the APRN practiced under the delegated prescriptive authority of that physician before November 1, 2013.

§222.6. Prescribing at Facility-Based Practices.

(a) An APRN with full licensure and a valid prescriptive authorization number may order or prescribe a drug or device at a facility based practice pursuant to a prescriptive authority agreement or through protocols or other written authorization developed in accordance with facility medical staff policies.

(1) If ordering or prescribing at a facility based practice pursuant to a prescriptive authority agreement, the APRN must maintain a prescriptive authority agreement that meets the requirements of §222.5 (relating to Prescriptive Authority

Agreement) of this chapter.

(2) If ordering or prescribing at a facility based practice pursuant to protocols or other written authorization developed in accordance with facility medical staff policies, the APRN must:

(A) review the authorizing documents with the appropriate medical staff at least annually;

(B) order or prescribe drugs and devices in a hospital based facility in which the delegating physician is the medical director, the chief of medical staff, the chair of the credentialing committee, or a department chair, or a physician who consents to the request of the medical director or chief of the medical staff to delegate;

(C) order or prescribe drugs and devices in a long term care facility in which the delegating physician is the medical director; and

(D) order or prescribe drugs and devices for the care or treatment of only those patients for whom physicians have given their prior consent.

(b) Protocols or other written authorization is authorization to provide medical aspects of patient care that are agreed upon and signed by the APRN and the physician, reviewed and signed at least annually, and maintained in the practice setting of the APRN. Protocols or other written authorization shall be defined to promote the exercise of professional judgment by the APRN commensurate with his/her education and experience. Protocols or other written authorization need not describe the exact steps that the APRN must take with respect to each specific condition, disease, or symptom and may state types or categories of drugs or devices that may be ordered or prescribed.

(c) A facility based physician may not be prohibited from delegating the prescribing

or ordering of drugs or devices to an APRN under §157.0512, Occupations Code or §222.5 of this chapter at other practice locations, including hospitals or long term care facilities, provided that the delegation at those locations complies with all of the requirements of §157.0512 and §222.5 of this chapter.

§222.7. Authority to Order and Prescribe Non-prescription Drugs, Dangerous Drugs, and Devices. An APRN who has been issued full licensure and a valid prescription

authorization number by the Board may order or prescribe non-prescription drugs, dangerous drugs, and devices, including durable medical equipment, in accordance with the standards and requirements set forth in this chapter. However, if the APRN wishes to also order or prescribe controlled substances, the APRN must also meet the additional requirements of §222.8 of this chapter.

§222.8. Authority to Order and Prescribe Controlled Substances.

(a) APRNs with full licensure and a valid prescription authorization number are eligible to obtain authority to order and prescribe certain categories of controlled substances. The APRN must comply with all federal and state laws and regulations relating to the ordering and prescribing of controlled substances in Texas, including but not limited to, requirements set forth by the Texas Department of Public Safety and the United States Drug Enforcement Administration.

(b) Orders and prescriptions for controlled substances in Schedules III through V may be authorized, provided the following criteria are met:

(1) Prescriptions for a controlled substance in Schedules III through V, including a refill of the prescription, shall not exceed a 90 day supply. This requirement includes a prescription, either in the form of a new prescription or in the form of a refill,

for the same controlled substance that a patient has been previously issued within the time period described by this subsection.

(2) Beyond the initial 90 days, the refill of a prescription for a controlled substance in Schedules III through V shall not be authorized prior to consultation with the delegating physician and notation of the consultation in the patient's chart.

(3) A prescription of a controlled substance in Schedules III through V shall not be authorized for a child less than two years of age prior to consultation with the delegating physician and notation of the consultation in the patient's chart.

(c) Orders and prescriptions for controlled substances in Schedule II may be authorized only:

(1) in a hospital facility-based practice, in accordance with policies approved by the hospital's medical staff or a committee of the hospital's medical staff as provided by the hospital's bylaws to ensure patient safety and as part of care provided to a patient who:

(A) has been admitted to the hospital for an intended length of stay of 24 hours or greater; or

(B) is receiving services in the emergency department of the hospital; or

(2) as part of the plan of care for the treatment of a person who has executed a written certification of a terminal illness, has elected to receive hospice care, and is receiving hospice treatment from a qualified hospice provider.

subsection (d) deleted.

§222.9. Conditions for Obtaining and Distributing Drug Samples. The APRN with full

licensure and a valid prescription authorization number may request, receive, possess, and distribute prescription drug samples provided:

(1) all requirements for the APRN to order and prescribe medications and devices are met;

(2) a prescriptive authority agreement or facility-based protocols or other written authorization authorizes the APRN to order and prescribe the medications and devices;

(3) the samples are for only those drugs or devices that the APRN is eligible to order or prescribe in accordance with the standards and requirements set forth in this chapter; and

(4) a record of the sample is maintained and samples are labeled as specified in the Dangerous Drug Act (Chapter 483, Health and Safety Code) or the Texas Controlled Substances Act (Chapter 481, Health and Safety Code) and 37 Texas Administrative Code Chapter 13.

§222.10. Enforcement.

(a) Any APRN who violates the sections of this rule or orders or prescribes in a manner that is not consistent with the standard of care shall be subject to removal of the authority to **order or** prescribe under this section and disciplinary action by the Board.

Behaviors associated with ordering and prescribing medications for which the Board may impose disciplinary action include, but are not limited to:

(1) ordering, prescribing, dispensing, or administering medications or devices for other than evidenced based therapeutic or prophylactic purposes that meet the minimum standards of care;

(2) ordering, prescribing, or dispensing medications or devices for

personal use;

(3) failing to properly assess and document the assessment prior to ordering, prescribing, dispensing, or administering a medication or device;

(4) selling, purchasing, trading, or offering to sell, purchase, or trade a prescription drug sample; and

(5) delegation of authority to any other person to order, prescribe, or dispense of an order or prescription for a drug or device.

(b) Failure to cooperate with a representative of the Board who conducts an onsite investigation may result in disciplinary action. Failure to cooperate with a representative of the Board or the Texas Medical Board who inspects and audits the practice relating to the implementation and operation of the prescriptive authority agreement may result in disciplinary action.

(c) The Board shall immediately notify the Texas Medical Board and the Texas Physician Assistant Board:

(1) when an APRN licensed by the Board becomes the subject of an investigation involving the delegation and supervision of prescriptive authority; and

(2) upon the final disposition of an investigation involving an APRN licensed by the Board and the delegation and supervision of prescriptive authority.

(d) Upon receipt of notice from the Texas Medical Board and/or the Texas Physician Assistant Board that a licensee of one of those boards is under investigation involving the delegation and supervision of prescriptive authority, the Board may open an investigation against an APRN who is a party to the prescriptive authority agreement with the licensee who is under investigation by the board that provided the notice.

(e) The Board shall report to the Texas Department of Public Safety and the United States Drug Enforcement Administration any of the following:

(1) any significant changes in the status of the RN license or advanced practice license; or

(2) disciplinary action impacting an APRN's ability to authorize or issue prescription drug orders **and medication orders**.

(f) The practice of the APRN approved by the Board **to order and prescribe** is subject to monitoring by the Board on a periodic basis.

(g) The Board shall maintain a list of APRNs who have been subject to a final adverse disciplinary action for an act involving the delegation and supervision of prescriptive authority.

(h) The Board shall provide information to the public regarding APRNs who are prohibited from entering into or practicing under a prescriptive authority agreement.

Proposed Text

§222.1. Definitions. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

(1) Advanced health assessment--A course that offers content supported by related clinical experience such that students gain the knowledge and skills needed to perform comprehensive assessments to acquire data, make diagnoses of health status, and formulate effective clinical management plans. Content must include assessment of all human systems, advanced assessment techniques, concepts, and approaches.

(2) Advanced Pharmacotherapeutics--A course that offers advanced content in pharmacokinetics, pharmacodynamics, pharmacotherapeutics of all broad categories of agents, and the application of drug therapy to the treatment of disease and/or the promotion of health.

(3) Advanced Physiology and Pathophysiology--A dedicated, comprehensive, system-focused pathology course(s) that provides students with the knowledge and skills to analyze the relationship between normal physiology and pathological phenomena produced by altered states across the life span.

(4) Advanced practice registered nurse (APRN)--A registered nurse who:

(A) has completed a graduate-level advanced practice nursing education program that prepares him/her for one of the four APRN roles;

(B) has passed a national certification examination recognized by the Board that measures APRN role and population focused competencies;

(C) maintains continued competence as evidenced by re-

certification/certification maintenance in the role and population focus through the national certification program;

(D) practices by building on the competencies of registered nurses by demonstrating a greater depth and breadth of knowledge, a greater synthesis of data, and greater role autonomy, as permitted by state law;

(E) is educationally prepared to assume responsibility and accountability for health promotion and/or maintenance, as well as the assessment, diagnosis, and management of patient problems, including the use and prescription of pharmacologic and non-pharmacologic interventions in compliance with state law;

(F) has clinical experience of sufficient depth and breadth to reflect the intended practice; and

(G) has been granted a license to practice as an APRN in one of the four APRN roles and at least one population focus area recognized by the Board.

(5) Board--The Texas Board of Nursing.

(6) Controlled Substance--A substance, including a drug, adulterant, and dilutant, listed in Schedules I through V or Penalty Groups 1, 1-A, or 2 through 4 of Chapter 481, Health and Safety Code (Texas Controlled Substances Act). The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance.

(7) Dangerous Drug--A device or drug that is unsafe for self-medication and that is not included in Schedules I through V or Penalty Groups 1 through 4 of Chapter 481, Health and Safety Code (Texas Controlled Substances Act). The term includes a device

or drug that bears, or is required to bear, the legend: “Caution: federal law prohibits dispensing without prescription” or “Rx only” or another legend that complies with federal law.

(8) Device--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. The term includes durable medical equipment.

(9) Diagnosis and management course--A course offering both didactic and clinical content in clinical decision-making and aspects of medical diagnosis and medical management of diseases and conditions. Supervised clinical practice must include the opportunity to provide pharmacological and non-pharmacological management of diseases and conditions considered within the scope of practice of the APRN's population focus area and role.

(10) Durable medical equipment--Equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (A) can withstand repeated use;
- (B) is primarily and customarily used to serve a medical purpose;
- (C) generally is not useful to an individual in the absence of an illness or injury; and
- (D) is appropriate for use in the home.

(11) Facility-based practice site--A licensed hospital or licensed long term care facility that serves as the practice location for the APRN.

(12) General hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals requiring diagnosis, treatment, or care for illness, injury, deformity, abnormality, or pregnancy; and

(B) regularly maintains, at a minimum, clinical laboratory services, diagnostic x-ray services, treatment facilities, including surgery or obstetrical care or both, and other definitive medical or surgical treatment of similar extent.

(13) Health professional shortage area--

(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 non-profit private medical facility or other facility that the Secretary of Health and Human Services determines has a health profession shortage as described by 42 U.S.C. §254e(a)(1).

(14) 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 a state; or

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

(B) has an organized medical staff.

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

(16) Non-prescription drug--A non-narcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.

(17) 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 non-profit health organization certified by the Texas Medical Board that complies with the requirements of Chapter 162, Occupations Code.

(18) Population focus area--The section of the population with which the APRN has been licensed to practice by the Board.

(19) Practice serving a medically under-served population--

(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(1)(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 APRN or physician assistant on or before March 1, 2013, based on the practice qualifying as a site serving a medically under-served population.

(20) Prescribe or order a drug or device--Determining the dangerous drugs, controlled substances, or devices that shall be used by or administered to a patient exercised in compliance with state and federal law, including the issuance of a prescription drug order or a medication order.

(21) Prescription drug--

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

(22) Prescriptive authority agreement--An agreement entered into by an APRN and a physician through which the physician delegates the act of prescribing or ordering a drug or device to the APRN.

(23) Protocols or other written authorization--Written authorization to provide medical aspects of patient care that are agreed upon and signed by the APRN and collaborating physician, reviewed and signed at least annually, and maintained in the

practice setting of the APRN. Protocols or other written authorization shall be defined to promote the exercise of professional judgment by the APRN commensurate with his/her education and experience. Such protocols or other written authorization need not describe the exact steps that the APRN must take with respect to each specific condition, disease, or symptom and may state types or categories of drugs that may be prescribed rather than just list specific drugs.

(24) Shall and must--Mandatory requirements.

(25) Should--A recommendation.

(26) Special hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals who are regularly admitted, treated, and discharged and who require services more intensive than room, board, personal services, and general nursing care;

(B) has clinical laboratory facilities, diagnostic x-ray facilities, treatment facilities, or other definitive medical treatment;

(C) has a medical staff in regular attendance as required by the rules of the Department of State Health Services; and

(D) maintains records of the clinical work performed for each patient.

§222.2. Approval for Prescriptive Authority.

(a) To be issued a prescription authorization number to prescribe or order a drug or device, a registered nurse (RN) shall:

(1) have full licensure from the Board to practice as an APRN. RNs with

Interim Approval to practice as APRNs are not eligible for prescriptive authority; and

(2) file a complete application for Prescriptive Authority and submit such evidence as required by the Board to verify successful completion of graduate level courses in advanced pharmacotherapeutics, advanced pathophysiology, advanced health assessment, and diagnosis and management of diseases and conditions within the role and population focus area.

(A) Nurse Practitioners, Nurse-Midwives, and Nurse Anesthetists will be considered to have met the course requirements of this section on the basis of courses completed in the advanced practice nursing educational program.

(B) Clinical Nurse Specialists shall submit documentation of successful completion of separate, dedicated, graduate level courses in the content areas described in paragraph (2) of this subsection. These courses shall be academic courses with a minimum of 45 clock hours per course from a nursing program accredited by an organization recognized by the Board.

(C) Clinical Nurse Specialists who were previously approved by the Board as APRNs by petition on the basis of completion of a non-nursing master's degree shall not be eligible for prescriptive authority.

(b) APRNs applying for prescriptive authority on the basis of endorsement of advanced practice licensure and prescriptive authority issued in another state must provide evidence that all education requirements for prescriptive authority in this state have been met.

§222.3. Renewal of Prescriptive Authority.

(a) The APRN shall renew the privilege to sign prescription drug orders in conjunction with the RN and advanced practice license renewal application.

(b) The APRN seeking to maintain prescriptive authority shall attest, on forms provided by the Board, to completing at least five contact hours of continuing education in pharmacotherapeutics within the preceding biennium. Those APRNs seeking to maintain prescriptive authority who order or prescribe controlled substances shall attest, on forms provided by the Board, to completing at least three additional contact hours of continuing education related to prescribing controlled substances within the preceding biennium.

(c) The continuing education requirements in subsection (b) of this section shall be in addition to continuing education required under Chapter 216 of this title (relating to Continuing Competency).

§222.4. Minimum Standards for Prescribing or Ordering Drugs and Devices.

(a) The APRN with a valid prescription authorization number shall:

(1) order or prescribe only those drugs or devices that are:

(A) authorized by a prescriptive authority agreement or, if practicing in a facility-based practice, authorized by either a prescriptive authority agreement or protocols or other written authorization; and

(B) ordered or prescribed for patient populations within the accepted scope of professional practice for the APRN's license;

(2) comply with the requirements for chart reviews specified in the prescriptive authority agreement and periodic face to face meetings set forth in this chapter; and

(3) comply with the requirements set forth in protocols or other written authorization if ordering or prescribing drugs or devices under facility-based protocols or other written authorization.

(b) Prescription Information. The format and essential elements of a prescription drug order shall comply with the requirements of the Texas State Board of Pharmacy. The following information must be provided on each prescription:

(1) the patient's name and address;

(2) the name, strength, and quantity of the drug to be dispensed;

(3) directions to the patient regarding taking of the drug and the dosage;

(4) the intended use of the drug, if appropriate;

(5) the name, address, and telephone number of the physician with whom the APRN has a prescriptive authority agreement or facility-based protocols or other written authorization;

(6) address and telephone number of the site at which the prescription drug order was issued;

(7) the date of issuance;

(8) the number of refills permitted;

(9) the name, prescription authorization number, and original signature of the APRN who authorized the prescription drug order; and

(10) the United States Drug Enforcement Administration numbers of the APRN and the collaborating physician, if the prescription drug order is for a controlled

substance.

(c) Generic Substitution. The APRN shall authorize or prevent generic substitution on a prescription in compliance with the current rules of the Texas State Board of Pharmacy relating to generic substitution.

(d) An APRN may order or prescribe medications for sexually transmitted diseases for partners of an established patient, if the APRN assesses the patient and determines that the patient may have been infected with a sexually transmitted disease. Nothing in this subsection shall be construed to require the APRN to issue prescriptions for partners of patients.

(e) APRNs may order or prescribe only those medications that are FDA approved unless done through protocol registration in a United States Institutional Review Board or Expanded Access authorized clinical trial. "Off label" use, or prescription of FDA-approved medications for uses other than that indicated by the FDA, is permitted when such practices are:

(1) within the current standard of care for treatment of the disease or condition; and

(2) supported by evidence-based research.

(f) The APRN with prescriptive authority shall cooperate with representatives of the Board and the Texas Medical Board during an inspection and audit relating to the operation and implementation of a prescriptive authority agreement.

§222.5. Prescriptive Authority Agreement.

(a) The prescriptive authority agreement is the mechanism by which an APRN is

delegated the authority to order or prescribe drugs or devices by a physician.

(b) An APRN with prescriptive authority and a physician are eligible to enter into or be parties to a prescriptive authority agreement only if the APRN:

(1) holds an active license to practice in this state that is in good standing.

For purposes of this chapter, good standing means that the nurse's license is not in delinquent status and that there is no current disciplinary action, disciplinary probation, or pending investigation(s) on his/her nursing license(s) or authorization(s);

(2) is not currently prohibited by the Board from executing a prescriptive authority agreement; and

(3) before executing the prescriptive authority agreement, the APRN and the physician disclose to the other prospective party to the agreement any prior disciplinary action by the applicable licensing board.

(c) A 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 either:

(A) the types or categories of drugs or devices that may be prescribed;

or

(B) the types of 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 APRN and the physician related to the care and treatment of patients;

(8) designate one or more alternate physicians who may participate in the execution of the prescriptive authority agreement in accordance with the rules of the Texas Medical Board if an alternate physician arrangement is to be utilized; 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 APRN and physician; and

(B) periodic face to face meetings between the APRN and the physician at a location agreed upon by both providers.

(d) The periodic face to face meetings described by subsection (c)(9)(B) of this section must:

(1) include:

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

(B) discussion of patient care improvement; and

(2) be documented and occur:

(A) except as provided by subparagraph (B) of this paragraph:

(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 video conferencing technology or the internet; or

(B) if during the seven years preceding the date the agreement is executed, the APRN was in a practice for at least five years that included the exercise of prescriptive authority with required physician supervision:

(i) at least monthly until the first anniversary of the date the agreement was 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 video conferencing technology or the internet.

(e) Although a prescriptive authority agreement must include the information specified by this section, the agreement may include other provisions agreed to by the APRN and physician, including provisions that were previously contained in protocols or other written authorization.

(f) The APRN shall participate in quality assurance meetings with an alternate physician in a physician group practice if the alternate physician has been designated to conduct and document the meeting.

(g) The prescriptive authority agreement is not required to describe the exact steps that an APRN must take with respect to each specific condition, disease, or symptom.

(h) An APRN 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.

(i) A party to the prescriptive authority agreement may not by contract waive, void, or nullify any provision of this rule.

(j) 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 respective licensing board, the individual shall immediately notify the other party to the prescriptive authority agreement.

(k) 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 shall be made available to the Board, the Texas Medical Board, or the Texas Physician Assistant Board not later than the third business day after the date of receipt of the request from the respective licensing board.

(l) The prescriptive authority agreement should promote the exercise of professional judgment by the APRN commensurate with the APRN's education and experience and the relationship between the APRN and the physician.

§222.6. Prescribing at Facility-Based Practice Sites.

(a) When ordering or prescribing a drug or device at a facility-based practice site,

the APRN with prescriptive authority shall:

(1) maintain either a prescriptive authority agreement that meets the requirements of this section or protocols or other written authorization developed in accordance with facility medical staff policies and review the authorizing documents with the appropriate medical staff at least annually;

(2) order or prescribe drugs and devices in a hospital-based facility in which the delegating physician is the medical director, the chief of medical staff, the chair of the credentialing committee, or a department chair, or a physician who consents to the request of the medical director or chief of the medical staff to delegate;

(3) order or prescribe drugs and devices in a long-term care facility in which the delegating physician is the medical director; and

(4) order or prescribe drugs and devices for the care or treatment of only those patients for whom physicians have given their prior consent.

(b) Protocols or other written authorization is authorization to provide medical aspects of patient care that are agreed upon and signed by the APRN and the physician, reviewed and signed at least annually, and maintained in the practice setting of the APRN. Protocols or other written authorization shall be defined to promote the exercise of professional judgment by the APRN commensurate with his/her education and experience. Protocols or other written authorization need not describe the exact steps that the APRN must take with respect to each specific condition, disease, or symptom and may state types or categories of drugs that may be ordered or prescribed.

§222.7. Orders and Prescriptions for Non-prescription Drugs, Dangerous Drugs, and

Devices. APRNs with full licensure and valid prescription authorization numbers are eligible to order or prescribe non-prescription drugs, dangerous drugs, and devices, including durable medical equipment, in accordance with the standards and requirements set forth in this chapter. APRNs with full licensure and valid prescription authorization numbers are not eligible to order or prescribe controlled substances unless they meet the applicable requirements of this rule.

§222.8. Orders and Prescriptions for Controlled Substances.

(a) APRNs with full licensure and valid prescription authorization numbers are eligible to obtain authority to order and prescribe certain categories of controlled substances. The APRN must comply with all federal and state laws and regulations relating to the ordering and prescribing of controlled substances in Texas, including but not limited to, requirements set forth by the Texas Department of Public Safety and the United States Drug Enforcement Administration.

(b) Orders and prescriptions for controlled substances in Schedules III through V may be authorized, provided the following criteria are met:

(1) Prescriptions for a controlled substance in Schedules III through V, including a refill of the prescription, shall not exceed a 90 day supply. This requirement includes a prescription, either in the form of a new prescription or in the form of a refill, for the same controlled substance that a patient has been previously issued within the time period described by this subsection.

(2) Beyond the initial 90 days, the refill of a prescription for a controlled substance in Schedules III through V shall not be authorized prior to consultation with the delegating physician and notation of the consultation in the patient's chart.

(3) A prescription of a controlled substance in Schedules III through V shall not be authorized for a child less than two years of age prior to consultation with the delegating physician and notation of the consultation in the patient's chart.

(c) Orders and prescriptions for controlled substances in Schedule II may be authorized only:

(1) in a hospital facility-based practice, in accordance with policies approved by the hospital's medical staff or a committee of the hospital's medical staff as provided by the hospital's bylaws to ensure patient safety and as part of care provided to a patient who:

(A) has been admitted to the hospital for an intended length of stay of 24 hours or greater; or

(B) is receiving services in the emergency department of the hospital;
or

(2) as part of the plan of care for the treatment of a person who has executed a written certification of a terminal illness, has elected to receive hospice care, and is receiving hospice treatment from a qualified hospice provider.

(d) APRNs with full licensure and valid prescription authorization must comply with all federal and state laws and regulations relating to the prescribing of controlled substances in Texas, including but not limited to, requirements set forth by the Texas Department of Public Safety and the United States Drug Enforcement Administration.

§222.9. Conditions for Obtaining and Distributing Drug Samples. The APRN with full licensure and a valid prescription authorization number may request, receive, possess, and distribute prescription drug samples provided:

(1) all requirements for the APRN to order and prescribe medications and devices are met;

(2) a prescriptive authority agreement or facility-based protocols or other written authorization authorizes the APRN to order and prescribe the medications and devices;

(3) the samples are for only those drugs or devices that the APRN is eligible to order or prescribe in accordance with the standards and requirements set forth in this chapter; and

(4) a record of the sample is maintained and samples are labeled as specified in the Dangerous Drug Act (Chapter 483, Health and Safety Code) or the Texas Controlled Substances Act (Chapter 481, Health and Safety Code) and 37 Texas Administrative Code Chapter 13.

§222.10. Enforcement.

(a) Any APRN who violates the sections of this rule or orders or prescribes in a manner that is not consistent with the standard of care shall be subject to removal of the authority to prescribe under this section and disciplinary action by the Board. Behaviors associated with ordering and prescribing medications for which the Board may impose disciplinary action include, but are not limited to:

(1) ordering, prescribing, dispensing, or administering medications or devices for other than evidenced based therapeutic or prophylactic purposes that meet the minimum standards of care;

(2) ordering, prescribing, or dispensing medications or devices for personal use;

(3) failing to properly assess and document the assessment prior to ordering, prescribing, dispensing, or administering a medication or device;

(4) selling, purchasing, trading, or offering to sell, purchase, or trade a prescription drug sample; and

(5) delegation of authority to any other person to order, prescribe, or dispense of an order or prescription for a drug or device.

(b) Failure to cooperate with a representative of the Board who conducts an onsite investigation may result in disciplinary action. Failure to cooperate with a representative of the Board or the Texas Medical Board who inspects and audits the practice relating to the implementation and operation of the prescriptive authority agreement may result in disciplinary action.

(c) The Board shall immediately notify the Texas Medical Board and the Texas Physician Assistant Board:

(1) when an APRN licensed by the Board becomes the subject of an investigation involving the delegation and supervision of prescriptive authority; and

(2) upon the final disposition of an investigation involving an APRN licensed by the Board and the delegation and supervision of prescriptive authority.

(d) Upon receipt of notice from the Texas Medical Board and/or the Texas Physician Assistant Board that a licensee of one of those boards is under investigation involving the delegation and supervision of prescriptive authority, the Board may open an investigation against an APRN who is a party to the prescriptive authority agreement with the licensee who is under investigation by the board that provided the notice.

(e) The Board shall report to the Texas Department of Public Safety and the United States Drug Enforcement Administration any of the following:

(1) any significant changes in the status of the RN license or advanced practice license; or

(2) disciplinary action impacting an APRN's ability to authorize or issue prescription drug orders.

(f) The practice of the APRN approved by the Board to sign prescription drug orders is subject to monitoring by the Board on a periodic basis.

(g) The Board shall maintain a list of APRNs who have been subject to a final adverse disciplinary action for an act involving the delegation and supervision of prescriptive authority.

(h) The Board shall provide information to the public regarding APRNs who are prohibited from entering into or practicing under a prescriptive authority agreement.