

Consideration of Adoption of Proposed Amendments to 22 Tex. Admin. Code Chapter 222, Pertaining to *Advanced Practice Nurses with Prescriptive Authority*, Written Comments Received, and Board Responses to Comments

Summary of Request: Consider final adoption of proposed amendments to 22 Tex. Admin. Code Chapter 222, pertaining to *Advanced Practice Nurses with Prescriptive Authority*. The proposed amendments to Chapter 222 were approved by the Board at its October 22-23, 2009, meeting for submission to the *Texas Register* for public comment. The proposed amendments were published in the *Texas Register* on November 27, 2009, and the comment period ended on December 27, 2009. The Board did not receive any written comments on the proposal. However, Staff has identified two typographical errors in the text of the rule as proposed.

Staff's suggested changes to the rule text to correct the typographical errors are attached hereto as Attachment "A". First, the word "subsection" in §222.2(a)(2)(A)(ii) has been changed to "subparagraph" and the reference to "(a)" has been restored to "(A)". This change is necessary to correctly reference §222.2(a)(2)(A), which describes the content areas referenced in §222.2(a)(2)(A)(ii). Second, the word "shall" in §222.7(4) has been struck in order to eliminate redundancy. Attachment "B" contains excerpts from the rule text as proposed for comparison.

The proposed amendments to Chapter 222 clarify changes made to the Medical Practice Act by Senate Bill (SB) 532, enacted by the 81st Legislature, Regular Session, effective September 1, 2009, which amends the Occupations Code Chapter 157 and provide guidance to advanced practice registered nurses (APRNs) who exercise prescriptive authority in this state.

Staff's Recommendation: Move to adopt the proposed amendments to 22 Tex. Admin. Code Chapter 222, pertaining to *Advanced Practice Nurses with Prescriptive Authority*, with changes. Further, move to adopt the changes to the proposed rule text as outlined in Attachment "A" and authorize Staff to publish the revised rule text in the *Texas Register*, with authority for General Counsel to make editorial changes as necessary to clarify rule and Board intent and to comply with the formatting requirements of the *Texas Register*.

Attachment “A”

§222.2. Approval for Prescriptive Authority.

(a) Credentials: To be approved by the Board to sign prescription drug orders and issued a prescription authorization number, a Registered Nurse (RN) shall:

(1) have full licensure from the Board to practice as an advanced practice registered nurse. RNs with Interim Approval to practice as advanced practice registered nurses are not eligible for prescriptive authority.

(2) file a complete application for Prescriptive Authority and submit such evidence as required by the Board to verify the following educational qualifications:

(A) To be eligible for Prescriptive Authority, advanced practice registered nurses must have successfully completed 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.

(i) 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.

(ii) Clinical Nurse Specialists shall submit documentation of successful completion of separate, dedicated, graduate level courses in the content areas described in **subparagraph (A)** of this section. 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.

(iii) The Board, by policy, may determine that certain specialties

of Clinical Nurse Specialists meet one or more of the course requirements on the basis of the advanced practice nursing educational program.

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

§222.7. Prescribing at Sites Serving Certain Medically Underserved Populations.

When signing prescription drug orders at a site serving a medically underserved population, the advanced practice registered nurse shall:

(1) maintain Protocols or other written authorization that must be reviewed and signed by both the advanced practice registered nurse and the delegating physician at least annually;

(2) have access to the delegating physician or alternate delegating physician for consultation, assistance with medical emergencies, or patient referral;

(3) provide a daily status report to the physician on any problems or complications encountered that are not covered by protocol; and

(4) **be** available during on-site visits by the physician which shall occur at least once every 10 business days that the advanced practice registered nurse is on site providing care.

(16) Prescribing--Determining the dangerous drugs or controlled substances that shall be used by or administered to a patient exercised in compliance with state and federal law.

(17) [(44)] Protocols or other written authorization--Written authorization to provide medical aspects of patient care that are agreed upon and signed by the advanced practice registered nurse [APN] and the physician, reviewed and signed at least annually, and maintained in the practice setting of the advanced practice registered nurse [APN]. Protocols or other written authorization shall be defined to promote the exercise of professional judgment by the advanced practice registered nurse [APN] commensurate with his/her education and experience. Such protocols or other written authorization need not describe the exact steps that the advanced practice registered nurse [APN] 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.

(18) [(45)] Shall and must--Mandatory requirements.

(19) [(46)] Should--A recommendation.

(20) Signing a prescription drug order--Completing a prescription drug order presigned by the delegating physician or the signing of a prescription by an advanced practice registered nurse. The advanced practice registered nurse must be designated to the Texas Medical Board by the delegating physician as a person delegated to sign a prescription.

(21) [(47)] Site serving a medically underserved population--

(A) a site located in a medically underserved area;

(B) a site located in a health manpower shortage area;

(C) a clinic designated as a rural health clinic under 42 USC 1395x(aa);

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

(E) a site located in an area in which the Texas Department of State Health Services [Texas Department of Health] determines there is an insufficient number of physicians providing services to eligible clients of federal, state, or locally funded health care programs; or

(F) a site that the Texas Department of State Health Services [Texas Department of Health] determines serves a disproportionate number of clients eligible to participate in federal, state, or locally funded health care programs.

§222.2. *Approval for Prescriptive Authority.*

(a) Credentials: To be approved by the Board [board] to [carry out or] sign prescription drug orders and issued a prescription authorization number, a Registered Nurse (RN) shall:

(1) have full licensure from [or provisional authorization by] the Board [board] to practice as an advanced practice registered nurse. RNs with Interim Approval to practice as advanced practice registered nurses are not eligible for prescriptive authority.

[(A) RNs with provisional authorization to practice as graduate advanced practice nurses who are eligible for prescription authorization numbers shall be limited to prescribing for categories of dangerous drugs only.]

[(B) RNs with Interim Authorization to practice as advanced practice nurses are not eligible for a prescription authorization number.]

(2) file a complete application for Prescriptive Authority and submit such evidence as required by the Board [board] to verify the following educational qualifications:

(A) To be eligible for Prescriptive Authority, advanced practice registered nurses must have successfully completed graduate level courses in advanced pharmacotherapeutics, advanced pathophysiology, advanced health assessment, and diagnosis and management of diseases and conditions [problems] within the role and population focus area [clinical specialty].

(i) 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.

(ii) Clinical Nurse Specialists shall submit documentation of successful completion of separate, dedicated, graduate level courses in the content areas described in subsection (a) [(A)] of this section. 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 [regionally accredited institution with a minimum of 45 clock hours per course].

(iii) The Board [board], by policy, may determine that certain specialties of Clinical Nurse Specialists meet one or more of the course requirements on the basis of the advanced practice nursing educational program.

(B) Clinical Nurse Specialists who were previously [have been] approved by the Board [board] as advanced practice registered nurses by petition on the basis of completion of a non-nursing master's degree shall not be eligible for prescriptive authority.

(b) (No change.)

(c) Exceptions Granted by the Texas Medical [State] Board [of Medical Examiners]: Requirements for utilizing [limited] prescriptive authority may be modified or waived if a delegating physician has received a modification or waiver from the Texas Medical [State] Board [of Medical Examiners] of any site or supervision requirements for a physician to delegate the carrying out or signing of prescription drug orders to the advanced practice registered nurse.

§222.3. *Renewal of Prescriptive Authority.*

(a) The advanced practice registered nurse shall renew the privilege to [carry out or] sign prescription drug orders in conjunction with the RN and advanced practice license renewal application.

(b) The advanced practice registered nurse seeking to maintain prescriptive authority shall attest, on forms provided by the Board [board], to completing at least five contact hours of continuing education in pharmacotherapeutics within the preceding biennium.

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

§222.4. *Minimum Standards for [Carrying Out or] Signing Prescriptions.*

(a) The advanced practice registered nurse with a valid prescription authorization number:

(1) shall [carry out or] sign prescription drug orders for only those drugs that are:

(A) (No change.)

(B) prescribed for patient populations within the accepted scope of professional practice for the advanced practice registered nurse's license [~~specialty area~~]; and

(2) shall comply with the requirements for adequate physician supervision published in the rules of the Texas Medical Board [~~of Medical Examiners~~] relating to Delegation of the Carrying Out or Signing of Prescription Drug Orders to Physician Assistants and Advanced Practice Nurses as well as other applicable laws.~~]~~

(b) Protocols or other written authorization shall be defined in a manner that promotes the exercise of professional judgement by the advanced practice registered nurse commensurate with the education and experience of that person.

(1) A protocol or other written authorization:

(A) is not required to describe the exact steps that the advanced practice registered nurse must take with respect to each specific condition, disease, or symptom; and

(B) (No change.)

(2) Protocols or other written authorization shall be:

(A) [~~shall be~~] written, agreed upon and signed by the advanced practice registered nurse and the physician;

(B) (No change.)

(C) maintained in the practice setting of the advanced practice registered nurse.

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

(1) - (4) (No change.)

(5) the name, address, telephone number, and, if the prescription is for a controlled substance, the United States Drug Enforcement Administration [~~DEA~~] number of the delegating physician;

(6) - (8) (No change.)

(9) the name, prescription authorization number, original signature, and, if the prescription is for a controlled substance, the Texas Department of Public Safety and United States Drug Enforcement Administration numbers [~~DEA number~~] of the advanced practice registered nurse signing or co-signing the prescription drug order.

(d) Generic Substitution. The advanced practice registered nurse 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.

(e) An advanced practice registered nurse may prescribe medications for sexually transmitted diseases for partners of an established patient, if the advanced practice registered nurse 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 advanced practice registered nurse to issue prescriptions for partners of patients.

(f) Advanced practice registered nurses may 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.

§222.5. *Prescriptions for Dangerous Drugs.*

Advanced practice registered nurses with full licensure [~~or provisional authorization to practice~~] and valid prescription authorization numbers are eligible to [~~carry out or~~] sign prescription drugs orders for dangerous drugs in accordance with the standards and requirements set forth in this chapter.

§222.6. *Prescriptions for Controlled Substances.*

(a) Advanced practice registered nurses with full licensure [~~authorization to practice~~] and valid prescription authorization numbers are eligible to obtain authority to prescribe certain categories of controlled substances. The advanced practice registered nurse 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. [~~Graduate advanced practice nurses who hold provisional authorization to practice shall not authorize or issue prescriptions for controlled substances until they have been issued full authorization to practice by the board.~~]

(b) Advanced practice registered nurses, [~~with full authorization to practice and valid prescription authorization numbers~~] who authorize or issue prescriptions for controlled substances shall:

(1) Limit prescriptions for controlled substances to those medications listed in Schedules III through [~~IV, or~~] V as established by the commissioner of public health under Chapter 481, Health and Safety Code (Texas Controlled Substances Act);

(2) Issue prescriptions, including a refill of the prescription, for a period not to exceed 90 [~~30~~] days;

(3) Not authorize the refill of a prescription for a controlled substance beyond the initial 90 days prior to consultation with the delegating physician and notation of the consultation in the patient's chart; and

(4) (No change.)

(c) [~~All other standards and requirements as set forth in this chapter relating to carrying out or signing prescription drug orders by advanced practice nurses must be met. In addition, advanced~~] Advanced practice registered nurses with [~~full authorization to practice and~~] valid prescription authorization [~~numbers~~] must comply with all federal~~]~~ and state [~~and local~~] 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.

§222.7. *Prescribing at Sites Serving Certain Medically Underserved Populations.*

When [~~carrying out or~~] signing prescription drug orders at a site serving a medically underserved population, the advanced practice registered nurse **shall**:

(1) maintain Protocols or other written authorization that must be reviewed and signed by both the advanced practice registered nurse and the delegating physician at least annually;

(2) - (3) (No change.)

(4) **shall** be available during on-site visits by the physician which shall occur at least once every 10 business days that the advanced practice registered nurse is on site providing care.

§222.8. *Prescribing at Physicians' Primary Practice Sites.*