

**Consideration of Proposed Amendments to 22 Tex. Admin. Code § 222,  
Pertaining to Advanced Practice Nurses with Prescriptive Authority**

**Summary of Request:** Consider a request to propose amendments to Rule 222 for the purpose of aligning the rule with changes to the Texas Occupations Code as a result of the passage of Senate Bill (SB) 532.

**Historical Perspective:** SB 532, passed in the 81<sup>st</sup> Legislative Session, amends the section of the *Texas Occupations Code* that relates to physician delegation of prescriptive authority to advanced practice registered nurses. The bill is provided for the Board's consideration as Attachment A. Although the bill only amended the section of the *Occupations Code* that is more commonly known as the Medical Practice Act, it is important for advanced practice registered nurses to be aware of the changes that impact their prescriptive authority. Those sections of the bill that directly impact advanced practice registered nurses were discussed with the Advanced Practice Nursing Advisory Committee (APNAC) at two separate meetings. The APNAC's recommendations for proposed amendments to Rule 222 are provided for the Board's consideration in Attachment B.

While discussing recommendations for amendments to Rule 222, the APNAC discussed two additional amendments to the rule. The first proposed amendment clarifies that advanced practice registered nurses **may** issue prescriptions for treatment of sexually transmitted infections when an established patient has been assessed and is determined to potentially be infected with a sexually transmitted infection. The proposed rule language does not **require** advanced practice registered nurses to issue prescriptions for patients' partners. This language is similar to language that was added to the Texas Medical Board's rules earlier this year. Advanced practice registered nurses who elect to issue such prescriptions would still be required to do so in compliance with current laws relating to physician delegation of prescriptive authority.

The second proposed amendment requires advanced practice registered nurses with delegated prescriptive authority to limit their prescribing to medications that are FDA approved or are part of a US Institutional Review Board approved research protocol. "Off label" prescriptions would be acceptable provided such use is within the current standard of care for the disease or condition and there is evidenced based research to support such practices. Board staff have received an increased number of inquiries regarding prescribing of medications for "off label" use as well as prescribing medications that have not been approved by the FDA. The proposed language is similar to that included in the Texas Medical Board's rules.

Other key changes in proposed Rule 222 include:

- Changes to definitions based on the language of SB 532 or the Model Nursing Practice Act and Administrative Rules from the National Council of State Boards of Nursing,
- Requirements to include Texas Department of Public Safety (DPS) controlled substance registration numbers on prescriptions consistent with DPS regulations
- Prescriptions for controlled substances in Schedules 3 through 5 may provide a 90 day supply of medication

**Pros and Cons:** The proposed amendments to Rule 222 will provide advanced practice registered nurses with rule language that is consistent with the changes to state law regarding delegation of prescriptive authority to advanced practice registered nurses. SB 532 became effective September 1, 2009. The proposed amendments will provide guidance and direction to advanced practice registered nurses who exercise prescriptive authority. The APNAC discussed all proposed amendments to Rule 222 and approved the proposed language that is provided for the Board's consideration.

**Cons:** None

**Staff Recommendation:** Move to approve the proposed amendments to 22 Tex. Admin. Code Chapter 222, concerning *Advanced Practice Nurses with Prescriptive Authority* and authorize staff to publish the proposal in the *Texas Register* for a 30-day comment period, 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*. If no negative comments and no request for a public hearing are received, move to adopt the proposed amendments to 22 Tex. Admin. Code Chapter 222, concerning *Advanced Practice Nurses with Prescriptive Authority* as proposed.

AN ACT

relating to a physician's delegation of prescriptive authority to physician assistants or advanced practice nurses.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subsections (b) and (b-1), Section 157.0511, Occupations Code, are amended to read as follows:

(b) A physician may delegate the carrying out or signing of a prescription drug order for a controlled substance only if:

(1) the prescription is for a controlled substance listed in Schedule [~~Schedules~~] III, IV, or V as established by the commissioner of public health under Chapter 481, Health and Safety Code;

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

(3) with regard to the refill of a prescription, the refill is authorized after consultation with the delegating physician and the consultation is noted in the patient's chart; and

(4) with regard to a prescription for a child less than two years of age, the prescription is made after consultation with the delegating physician and the consultation is noted in the patient's chart.

(b-1) The board shall adopt rules that require a physician who delegates the carrying out or

signing of a prescription drug order under this subchapter to register with the board the name and license number of the physician assistant or advanced practice nurse [~~maintain records that show when and~~] to whom a delegation is made. The board may develop and use an electronic online delegation registration process for registration under this subsection [~~access the physician's records under this subsection as necessary for an investigation~~].

SECTION 2. Subsections (a) and (e), Section 157.053, Occupations Code, are amended to read as follows:

(a) In this section, "primary practice site" means:

(1) the practice location of a physician at which the physician spends the majority of the physician's time;

(2) a licensed hospital, a licensed long-term care facility, or a licensed adult care center where both the physician and the physician assistant or advanced practice nurse are authorized to practice;

(3) a clinic operated by or for the benefit of a public school district to provide care to the students of that district and the siblings of those students, if consent to treatment at that clinic is obtained in a manner that complies with Chapter 32, Family Code;

(4) the residence of an established patient; [~~or~~]

(5) another location at which the physician is physically present with the physician assistant or advanced practice nurse; or

(6) a location where a physician assistant or advanced practice nurse who practices on-site with the physician more than 50 percent of the time and in accordance with board rules provides:

(A) health care services for established patients;

(B) without remuneration, voluntary charity health care services at a clinic run or sponsored by a nonprofit organization; or

(C) without remuneration, voluntary health care services during a declared emergency or disaster at a temporary facility operated or sponsored by a governmental entity or nonprofit organization and established to serve persons in this state.

(e) A physician's authority to delegate the carrying out or signing of a prescription drug order is limited to:

(1) four [~~three~~] physician assistants or advanced practice nurses or their full-time equivalents practicing at the physician's primary practice site or at an alternate practice site under Section 157.0541 unless a waiver is granted under Section 157.0542(b-1); and

(2) the patients with whom the physician has established or will establish a physician-patient relationship.

SECTION 3. Subsection (b), Section 157.054, Occupations Code, is amended to read as follows:

(b) A physician's authority to delegate under Subsection (a) is limited as follows:

(1) the delegation must be made under a physician's order, standing medical order, standing delegation order, or another order or protocol developed in accordance with policies approved by the facility's medical staff or a committee of the facility's medical staff as provided by the facility bylaws;

(2) the delegation must 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;

(3) the delegation may not permit the carrying out or signing of prescription drug orders for the care or treatment of the patients of any other physician without the prior consent of that physician;

(4) delegation in a long-term care facility must be by the medical director and is limited to the carrying out and signing of prescription drug orders to not more than four [~~three~~] advanced practice nurses or physician assistants or their full-time equivalents; and

(5) a physician may not delegate at more than one licensed hospital or more than two long-term care facilities unless approved by the board.

SECTION 4. Subsections (a), (c), and (e), Section 157.0541, Occupations Code, are amended to read as follows:

(a) In this section, "alternate site" means a practice site:

(1) where services similar to the services provided at the delegating physician's primary practice site are provided; and

(2) located within 75 [~~60~~] miles of the delegating physician's residence or primary practice site.

(c) Physician supervision is adequate for the purposes of this section if [~~the delegating physician~~]:

(1) the delegating physician:

(A) is on-site with the advanced practice nurse or physician assistant at least 10 [20] percent of the hours of operation of the site each month that the physician assistant or advanced practice nurse is acting with delegated prescriptive authority and is available while on-site to see, diagnose, treat, and provide care to those patients for services provided or to be provided by the physician assistant or advanced practice nurse to whom the physician has delegated prescriptive

authority; and

(B) is not prohibited by contract from seeing, diagnosing, or treating a patient for services provided or to be provided by the physician assistant or advanced practice nurse under delegated prescriptive authority [time];

(2) the delegating physician reviews at least 10 percent of the medical charts, including through electronic review of the charts from a remote location, for each advanced practice nurse or physician assistant at the site; and

(3) the delegating physician is available through direct telecommunication for consultation, patient referral, or assistance with a medical emergency.

(e) Unless a waiver is granted under Section 157.0542(b-1), the [The] combined number of advanced practice nurses and physician assistants to whom a physician may delegate under this section and at a primary practice site under Section 157.053 may not exceed four [three] physician assistants or advanced practice nurses or the full-time equivalent of four [three] physician assistants or advanced practice nurses.

SECTION 5. Section 157.0542, Occupations Code, is amended by amending Subsection (a) and adding Subsections (b-1), (b-2), and (b-3) to read as follows:

(a) On determining that the conditions of Subsection (b) have been met, the board may waive or modify any of the site or supervision requirements for a physician to delegate the carrying out or signing of prescription drug orders to an advanced practice nurse or physician assistant under Sections 157.052, 157.053, 157.054, and 157.0541, or under board rules. The board may not waive the limitation on the number of primary or alternate practice sites at which a physician may delegate the carrying out or signing of prescription drug orders or the number of advanced practice nurses or

physician assistants to whom a physician may delegate the carrying out or signing of prescription drug orders, except as provided by Subsection (b-1)(1).

(b-1) If the board determines that the types of health care services provided by a physician assistant or advanced practice nurse under Section 157.0541 are limited in nature and duration and are within the scope of delegated authority under this subchapter, as defined by board rule, and that patient health care will not be adversely affected, the board may modify or waive:

(1) the limitation on the number of physician assistants or advanced practice nurses, or their full-time equivalents, if the board does not authorize more than six physician assistants or advanced practice nurses or their full-time equivalents;

(2) the mileage limitation; or

(3) the on-site supervision requirements, except that the physician must be available on-site at regular intervals and when on-site the physician must be available to treat patients.

(b-2) A modification or waiver granted under this section may not validate or authorize a contract provision that prohibits a physician from seeing, diagnosing, or treating any patient.

(b-3) In granting a modification or waiver under Subsection (b-1), the board may not limit the authority of the physician to delegate to less than the requirements established under Section 157.0541(a)(2) or Section 157.0541(e) or greater than the requirements established under Section 157.0541(c)(1)(A).

SECTION 6. Subsection (f), Section 157.059, Occupations Code, is amended to read as follows:

(f) The authority of a physician to delegate under this section is limited to:

(1) four [~~three~~] nurse midwives or physician assistants or their full-time equivalents;

and

(2) the designated facility at which the nurse midwife or physician assistant provides care.

SECTION 7. Not later than January 31, 2010, the Texas Medical Board shall adopt the rules necessary to implement Chapter 157, Occupations Code, as amended by this Act.

SECTION 8. This Act takes effect September 1, 2009.

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President of the Senate

\_\_\_\_\_  
Speaker of the House

I hereby certify that S.B. No. 532 passed the Senate on March 26, 2009, by the following vote: Yeas 31, Nays 0; and that the Senate concurred in House amendments on May 28, 2009, by the following vote: Yeas 31, Nays 0.

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Secretary of the Senate

I hereby certify that S.B. No. 532 passed the House, with amendments, on May 20, 2009, by the following vote: Yeas 145, Nays 0, two present not voting.

\_\_\_\_\_  
Chief Clerk of the House

Approved:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Governor

## **CHAPTER 222. ADVANCED PRACTICE REGISTERED NURSES WITH PRESCRIPTIVE AUTHORITY.**

### **§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 course--A course that offers content supported by related clinical experience such that students gain the knowledge and skills needed to perform comprehensive assessments, including histories and physical examinations, to make diagnoses and formulate effective clinical management plans.

~~[Advanced practice nurse--A registered nurse approved by the board to practice as an advanced practice nurse based on completing an advanced educational program acceptable to the board. The term includes a nurse practitioner, nurse-midwife, nurse anesthetist, and a clinical nurse specialist. The advanced practice nurse is prepared to practice in an expanded role to provide health care to individuals, families, and/or groups in a variety of settings including but not limited to homes, hospitals, institutions, offices, industry, schools, community agencies, public and private clinics, and private practice. The advanced practice nurse acts independently and/or in collaboration with other health care professionals in the delivery of health care services.]~~

(2) Advanced pathophysiology course--A course that offers content that provides a comprehensive, systems-based study of pathophysiology that provides students with the knowledge and skills to analyze the relationship between normal physiology and pathophysiological phenomena. ~~[Alternate site--A practice site:~~

~~(A) Where services similar to the services provided at the delegating physician's primary practice site are provided; and~~

~~(B) Located within 60 miles of the delegating physician's primary practice site.]~~

(3) Advanced pharmacotherapeutics course--A course that offers advanced content in pharmacokinetics and pharmacodynamics, encompassing a broad range of drug classifications, including the application of drug therapy to the treatment of disease and/or the promotion of health. [Board--The Board of Nurse Examiners for the State of Texas.]

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

(A) has completed a graduate-level education program accredited by an organization recognized by the Board that prepares him/her for one of the four following recognized advanced practice roles:

(i) nurse anesthetist,

(ii) nurse-midwife,

(iii) nurse practitioner; or

(iv) clinical nurse specialist;

(B) has demonstrated current competence by:

(i) passing a national certification examination recognized by the Board that measures advanced practice role and population-focused competencies and demonstrating continuing competence as evidenced by certification maintenance/recertification in the role and population through a national certification program; or

(ii) meeting requirements set forth by the Board for those advanced practice registered nurses not required by §221.7 of this title (relating to Petitions for Waiver and Exemptions) to hold national certification;

(C) has acquired advanced clinical knowledge and skills preparing him/her to provide direct and indirect care to patients with greater role autonomy;

(D) has been educationally prepared to assume responsibility and accountability for health promotion and/or maintenance as well as the assessment, diagnosis, and management of patient problems that includes the use and prescription of pharmacologic and non-pharmacologic interventions;

(E) has clinical experiences of sufficient depth and breadth to reflect the area of licensure; and

(F) holds current licensure in one of the four advanced practice roles and a Board-approved population focus area. [~~Carrying out or signing a prescription drug order--Completing a prescription drug order presigned by the delegating physician or signing (writing) a prescription by an advanced practice nurse after that person has been designated to the Board of Medical Examiners by the delegating physician as a person delegated to sign a prescription.~~]

(5) Alternate site--A practice site:

(A) where the services provided are similar to the services provided at the delegating physician's primary practice site; and

(B) located within 75 miles of the delegating physician's residence or primary practice site.

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

(7)~~(5)~~ Controlled substance--A substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Groups 1, 1-A, or 2 through 4 of chapter 481 Texas 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.

(8)~~(6)~~ Dangerous drug--A device or a drug that is unsafe for self medication and that is not included in schedules I-V or penalty groups I-IV of chapter 481 Texas Health and Safety Code (Texas Controlled Substances Act). The term includes a device or a drug that bears or is required to bear the legend: "Caution: federal law prohibits dispensing without prescription" or "RX only" or another legend that complies with federal law.

(9)~~(7)~~ 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 ~~[problems]~~ considered within the scope of practice of the advanced practice registered nurse's population focus area ~~[specialty]~~ and role.

(10)~~(8)~~ Eligible sites--Sites serving medically underserved populations; a physician's primary practice site; an alternate site; or a facility-based practice site.

(11)~~(9)~~ Facility-based practice site--A licensed hospital or licensed long term care facility that serves as the practice location for the advanced practice registered nurse.

(12)~~[(10)]~~ Health Manpower Shortage Area--An urban or rural area, population group, or public or nonprofit private medical facility or other facility that the Secretary of the United States Department of Health and Human Services (USDHHS) designates as having a health manpower shortage, as described by 42 USC Section 254e(a)(1) or a successor federal statute or regulation.

(13)~~[(11)]~~ Medically Underserved Area (MUA)--

(A) An urban or rural area or population group that the Secretary of the United States Department of Health and Human Services (USDHHS) designates as having a shortage of those services as described by 42 USC Section 300e-1(7) or a successor federal statute or regulation; or

(B) an area defined as medically underserved by rules adopted by the Texas Department of State Health Services ~~[Texas Board of Health (Texas Department of Health)]~~ based on demographics specific to this state ~~[State]~~, geographic factors that affect access to health care, and environmental health factors.

~~[(12) Pharmacotherapeutics course--A course that offers content in pharmacokinetics and pharmacodynamics, pharmacology of current/commonly used medications, and the application of drug therapy to the treatment of disease and/or the promotion of health.]~~

(14)~~[(13)]~~ Physician's primary practice site--

(A) the practice location at which the physician spends the majority of his/her ~~[the physician's]~~ time;

(B) a licensed hospital, a licensed long-term care facility, or a licensed adult care center where both the physician and the advanced practice registered nurse [APN] are authorized to practice;

(C) a clinic operated by or for the benefit of a public school district to provide care to the students of that district and the siblings of those students, if consent to treatment at that clinic is obtained in a manner that complies with Chapter 32, Family Code;

(D) the residence of an established patient; [or]

(E) another location at which the physician is physically present with the advanced practice registered nurse; and [.]

(F) provided an advanced practice registered nurse spends at least 50 percent of the time in a setting with the delegating physician, she/he may also prescribe in the following settings:

(i) a site in which health care services are provided for established patients only;

(ii) a clinic run or sponsored by a nonprofit organization that provides voluntary charity health care services where the advanced practice registered nurse is not remunerated; or

(iii) a setting where voluntary health care services are provided during a declared emergency or disaster at a temporary facility operated or sponsored by a governmental entity or nonprofit organization and established to serve persons in this state where the advanced practice registered nurse is not remunerated.

(15) Population focus area--The section of the population with which the advanced practice registered nurse has been licensed to practice by the Board.

(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)[(14)] 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)[(15)] Shall and must--Mandatory requirements.

(19)[(16)] 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)[(17)] 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 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) Sites: Prescribing privileges are limited to eligible sites to include sites serving certain medically underserved populations, physician's primary practice sites, alternate sites, and facility-based practice sites.

(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) authorized by Protocols or other written authorization for medical aspects of patient care; and

(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) may state types or categories of medications that may be prescribed or contain the types or categories of medications that may not be prescribed.

(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) reviewed and signed at least annually; and

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

(6) address and telephone number of the site at which the prescription drug order was carried out or signed;

(7) the date of issuance;

(8) the number of refills permitted; and

(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 [DEA] numbers [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) Not authorize the prescription of a controlled substance 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) 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) 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) 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.**

When [~~carrying out or~~] signing prescription drug orders at a physician's primary practice site, 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; and

(2) sign or co-sign prescription drug orders only for those patients with whom the physician has established or will establish a physician-patient relationship although the physician is not required to see the patient within a specified time period.

#### **§222.9. Prescribing at Alternate Sites.**

When [~~carrying out or~~] signing prescription drug orders at an alternate site, 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) be available on-site with the physician at least 10 [~~twenty~~] percent of the hours of operation of the site each month that the advanced practice registered nurse is acting with delegated prescriptive authority [~~time~~]; and

(3) have access to the delegating physician through direct telecommunication for consultation, patient referral, or assistance with a medical emergency.[:]

#### **§222.10. Prescribing at Facility-based Practice Sites.**

When [carrying out or] signing prescription drug orders at a facility-based practice site, the advanced practice registered nurse shall:

(1) maintain Protocols or other written authorization developed in accordance with facility medical staff policies and review [~~reviewing~~] the authorizing documents with the appropriate medical staff at least annually;

(2) sign or co-sign prescription drug orders in the 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; and

(3) sign or co-sign prescription drug orders for the care or treatment of only those patients for whom physicians have given their prior consent.

#### **§222.11. Conditions for Obtaining and Distributing Drug Samples.**

The advanced practice registered nurse with a valid prescription authorization number may request, receive, possess and distribute prescription drug samples provided:

(1) all requirements for the advanced practice registered nurse to sign prescription drug orders are met;

(2) Protocols or other physician orders authorize the advanced practice registered nurse to sign the prescription drug orders;

(3) the samples are for only those drugs that the advanced practice registered nurse is eligible to 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 (Health and Safety Code, Chapter 483) or the Controlled Substances Act (Health and Safety Code, Chapter 481) and 37 Texas Administrative Code, Chapter 13.

#### **§222.12. Enforcement.**

(a) Any advanced practice registered nurse who violates these rules 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 rule and disciplinary action by the Board [~~board~~] under Texas Occupations Code §301.452.

(b) The Board [~~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 [~~authorization~~], or

(2) Disciplinary action impacting an advanced practice registered nurse's ability to authorize or issue prescription drug orders.

(c) The practice of the advanced practice registered nurse approved by the board to [~~carry out or~~] sign prescription drug orders is subject to monitoring by the Board [~~board~~] on a periodic basis.