Agenda Item: 6.9
Board Meeting on October 21, 2021
Prepared by: Jena Abel

Consideration of proposal and adoption of rule review of 22 Texas Administrative Code §228.1 (relating to Standards of Practice), including written comments received; consideration of recommendations for related rule amendments to §228.1 made by the Advanced Practice Nursing Advisory Committee (APNAC); and consideration of proposed amendments to §228.1

Background: Board Rule 228.1 was reviewed in April 2018 as part of the Board's regular rule review required by Texas Government Code §2001.039. The rule review was published in the *Texas Register* on April 6, 2018, (43 TexReg 2167) for public comment. Comments were received from the APRN Alliance (Alliance). The Board considered the submitted comments at its July 2018 meeting and charged the APNAC with reviewing the comments and making recommendations regarding amendments to Rule 228.1.

The APNAC convened on December 10, 2018, to consider the Alliance's comments. The APNAC's recommendations were:

1. The Alliance requested clarification regarding whether the rule applied to the management of chronic pain, acute pain, or both. The APNAC spent a considerable amount of time discussing this issue at its meeting. The rule applies to the provision of pain management services, which includes the treatment of both chronic and acute pain. This was an intentional choice when the rule was first adopted. The text of the rule currently includes the phrase "as appropriate" in subsections (c) – (f), which allows for flexibility in the applicability of the rule's requirements in individualized practice settings. Further, a practitioner's reported conduct is examined in light of the prevailing standard of care, which the APNAC determined was appropriately reflected by the rule. As such, the APNAC decided not to recommend making any changes to the rule in this regard.

2. The Alliance requested that subsection (i)(1) and (2) be amended so as not to apply to APRNs. Subsection (i) applies to pain management clinics, as that term is defined in the Occupations Code §168.001. The Occupations Code §168.201(c) requires the owner or operator of a pain management clinic to be on-site at the clinic at least 33% of the clinic's total number of operating hours and to review at least 33% of the total number of patient files of the clinic, including the patient files of a clinic employee or contractor to whom authority for patient care has been delegated by the clinic. The original enactment of §228.1 made these requirements applicable to APRNs. The owner or operator of a pain management clinic, as defined by statute, does not include an APRN.

The rule was enacted during the height of the operation of pill mills, and the Board received complaints involving clinics where APRNs were working without any physician involvement, in some cases with no delegation agreements or collaboration. Requiring

on-site presence and additional chart review was intended to ensure appropriate delegation and collaboration in the interest of patient safety. Since the enactment of the rule, however, there has been a reduction in pill mill activity due to increased enforcement efforts, regulation of schedule II medications, and increased awareness at both the state and federal levels.

APRNs who prescribe are currently required by the Occupations Code Chapter 157 to meet prescriptive authority agreement and chart review requirements. The APNAC determined that the rule's requirements for additional chart review in a pain management clinic no longer serve the purpose for which it was originally enacted and is unnecessarily duplicative. Further, the APNAC determined that requiring an APRN to be on-site with a physician at a pain management clinic would be overly restrictive and unlikely to promote a safer patient environment. As such, the APNAC recommended striking subsection (i)(1) and (2) from the rule. In order to ensure APRNs that work in pain management clinics are aware of the requirements of Chapter 168, the APNAC also recommended including an FAQ on the Board's website outlining its requirements.

3. The Alliance recommended reversing the order of subsection (i)(4) and (5) for additional clarity. The APNAC agreed and recommended reversing the order of the subsection for additional clarity. Further, the APNAC recommended adding the phrase "otherwise would" to subsection (i)(4) to further clarify the statutory exemption.

Since the APNAC's meeting in 2018, however, Chapter 168 was amended and the prior exemption from which (i)(4) was derived no longer exists in statute. Therefore, Staff recommends removing (i)(4) from the rule in its entirety. Further, for consistency with the statutory change, Staff recommends slight editorial changes to (i)(5) as well.

Attachment "A" contains the proposed amendments to §228.1, as recommended by the APNAC and containing Staff's recommended edits to (i)(4) and (5). If the Board decides to approve the recommended amendments, the rule review for §228.1 will be completed following publication of the proposed amendments in the *Texas Register* and subsequent adoption by the Board following a public comment period.

Board Action: Move to approve the proposed amendments to 22 Texas Administrative Code §228.1, relating to *Standards of Practice,* as set out in Attachment "A", with authority for the 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 Texas Administrative Code §228.1, relating to *Standards of Practice, a*s proposed.

Further, direct Staff to prepare an FAQ as recommended by the APNAC.

Attachment “A”

Rule 228.1. Standards of Practice. (changes in yellow highlight)

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

(1) Controlled substance (also referred to as scheduled drugs)--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.

(2) 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. 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.

(3) 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.

(4) Medication--A dangerous drug, controlled substance, non-prescription drug, or device. For purposes of this chapter, the term also includes herbal and naturopathic remedies.

(5) 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.

(6) Pain management clinic--As defined in Chapter 168, Occupations Code.

(b) Purpose. This section sets forth the minimum standards of nursing practice for an advanced practice registered nurse (APRN) who provides pain management services.

(1) The goal of pain management is to therapeutically treat the patient's pain in relation to overall health, including physical function, psychological, social and work-related factors.

(2) Medications must be prescribed in a therapeutic manner that helps, rather than harms, the patient. Medications must be recognized to be pharmacologically appropriate and safe for the diagnosis for which the medication is being used.

(3) Proper treatment of pain must be based on careful and complete patient assessment and sound clinical judgment. Harm can result from failure to use sound clinical judgment, particularly in drug therapy. The APRN shall provide treatment of pain that is within the current standard of care and is supported by evidence based research.

(4) Documentation in patient records shall be legible, complete, and accurate. All consultations and referrals with the delegating physician and other health care providers shall be documented.

(5) Any treatment plan should be mutually agreed upon by the patient and the provider. Treatment of pain requires a reasonably detailed and documented plan of care to ensure that the patient's treatment is appropriately monitored. A documented explanation of the rationale for the particular treatment plan is required for cases in which

treatment with scheduled drugs is difficult to relate to the patient's objective physical, radiographic, or laboratory findings. Ongoing consultation and referral to the delegating physician and other health care providers shall be documented.

(c) Evaluation of the Patient Seeking Treatment for Pain.

(1) The APRN shall ensure that a current and complete health history is documented in the patient record. The APRN shall perform and document a physical assessment that includes a problem focused exam specific to the chief presenting complaint of the patient. At a minimum, this assessment must be performed and documented when prescribing and/or ordering a new medication or a refill of a medication for the patient.

(2) Pain assessment and documentation in the patient record shall include, as appropriate:

(A) The nature and intensity of the pain;

(B) All current and past treatments for pain, including relevant patient records from prior treating providers as available;

(C) Underlying conditions and co-existing physical and psychiatric disorders;

(D) The effect of pain on physical and psychological function;

(E) History and potential for substance misuse, abuse, dependence, addiction or other substance use disorder, including relevant validated, objective testing and risk stratification tools; and

(F) One or more recognized clinical indications for the use of a medication, if prescribed.

(d) Treatment Plan and Outcomes for Patients with Pain. The APRN who treats patients with pain shall ensure that there is a written treatment plan documented in the patient record. Information in the patient record shall include, as appropriate:

(1) A written explanation of how the medication(s) ordered/prescribed relate(s) to the chief presenting complaint and treatment of pain;

(2) The name, dosage, frequency, and quantity of any medication prescribed and number of refills authorized;

(3) Laboratory testing and diagnostic evaluations ordered;

(4) All other treatment options that are planned or considered;

(5) Plans for ongoing monitoring of the treatment plan and outcomes;

(6) Subjective and objective measures that will be used to determine treatment outcomes, such as pain relief and improved physical and psychosocial function;

(7) Any and all consultations and referrals, including the date the consultation and/or referral was made; to whom the consultation and/or referral was made; the time frame for completion of the consultation and/or referral; and the results of the consultation and/or referral; and

(8) Documentation of informed consent, as required by subsection (e) of this section.

(e) Informed consent includes a discussion with the patient, a person(s) designated by the patient, or with the patient's surrogate or guardian, if the patient is without medical decision-making capacity, of the risks and benefits of the use of medications for the treatment of pain. As appropriate, this discussion should be documented by either a written, signed document maintained in the patient record or a contemporaneous notation

included in the patient record. Discussion of risks and benefits should include an explanation of the following:

(1) Diagnosis;

(2) Treatment plan;

(3) Expected therapeutic outcomes, including the realistic expectations for sustained pain relief, and possibilities for lack of pain relief;

(4) Non-pharmacological therapies;

(5) Potential side effects of treatments and drug therapy and how to manage common side effects;

(6) Adverse effects of medication use, including the potential for dependence, addiction, tolerance, and withdrawal; and

(7) Potential for impaired judgment and motor skills.

(f) If the treatment plan includes drug therapy beyond 90 days, the use of a written pain management agreement should be included, as appropriate. The written pain management agreement should outline patient responsibilities that, at a minimum require the patient to:

(1) Submit to laboratory testing for drug confirmation upon request of the APRN, the delegating physician, and/or any other health care providers;

(2) Adhere to the number and frequency of prescription refills;

(3) Use only one provider to prescribe controlled substances related to pain management, and to make consultations and referrals;

(4) Use only one pharmacy for all prescriptions for controlled substances related to pain management;

(5) Acknowledge potential consequences of non-compliance with the agreement; and

(6) Acknowledge processes following successful completion of treatment goals, including weaning of medications.

(g) Ongoing monitoring of the treatment of pain.

(1) The APRN shall see the patient for periodic review of the treatment plan at reasonable intervals.

(2) The periodic review shall include an assessment of the patient's progress toward reaching treatment plan goals, taking into consideration the history of medication usage, as well as any new information about the pain, and the patient's compliance with the pain management agreement.

(3) Each periodic review of the treatment plan shall be documented in the patient record.

(4) Any adjustment in the treatment plan based on individual needs of the patient shall be documented.

(5) Continuation or modification of the use of medications for pain management shall be based on an evaluation of progress toward treatment plan goals, as well as evaluation and consideration of any new factors that may influence the treatment plan.

(A) Progress or lack of progress in relieving pain and meeting treatment objectives shall be documented in the patient record. Progress may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.

(B) Objective evidence of improved or diminished function shall be monitored. Information from the patient, family members, or other caregivers should be considered in determining the patient's response to treatment.

(C) If the patient's progress is unsatisfactory, the current treatment plan should be reevaluated, with consideration given to the use of other therapeutic modalities and/or services of other providers.

(6) Continuation of the use of scheduled drugs shall include consultation with the delegating physician and documentation of such consultation in the patient record, as required for delegation of prescriptive authority for controlled substances pursuant to §157.0511 and §168.201, Occupations Code.

(h) Consultation and Referral. In certain situations, further evaluation and treatment may be indicated.

(1) Patients who are at risk for substance use disorders or addiction require special attention. Consideration should be given to consultation with and/or referral to a provider who is an expert in the treatment of patients with substance use disorders.

(2) Patients with chronic pain and histories of substance use disorders or with co-existing psychological and/or psychiatric disorders may require consultation with and/or referral to an expert in the treatment of such patients. Consideration should be given to consultation with and/or referral to a provider who is an expert in the treatment of patients with these histories and/or disorders.

(3) Information regarding the consideration of consultation and/or referral under this subsection should be documented in the patient record.

(i) Pain management clinics in the state of Texas. Prior to providing pain management services in these settings, APRNs who practice in pain management clinics shall verify that the clinic has been properly certified as a pain management clinic by the Texas Medical Board and that the certification is current.

[~~(1) The APRN shall be available on site with the physician at least 33 percent of a pain management clinic's total operating hours.~~]

[~~(2) The APRN shall comply with the requirements of §168.201, Occupations Code for review of 33 percent of patient charts in pain management clinics.~~]

(1)[~~(3)~~] The APRN shall ensure that s/he is in compliance with all other requirements for delegation of prescriptive authority for medications as set forth in Board rule.

[~~(4) An APRN who owns or operates a clinic in this state that meets the definition of a pain management clinic under this section is exempt from the certification requirements of the Occupations Code Chapter 168 and the Texas Medical Board if:~~]

[~~(A) the APRN is treating patients in the APRN's area of specialty; and~~

[~~(B) the APRN personally uses other forms of treatment with the issuance of a prescription to the majority of the APRN's patients. A treatment under this subparagraph must be within the current standard of care, supported by evidence based research, and consistent with the treatment plan.~~]

(2)[~~(5)~~] APRNs shall not own or operate a pain management clinic. This prohibition does not apply to an APRN who owns or operates a clinic in this state that does not fall within [~~is exempt from~~] the certification requirements of the Occupations

Code Chapter 168 and the Texas Medical Board.

APRN Alliance

TEXAS NURSES ASSOCIATION | TNP Texas Nurse Practitioners | TxANA Texas Association of Nurse Anesthetists | TxCNS | CTCNM Consortium of Texas Certified Nurse Midwives

May 2, 2018

To:

Dusty Johnston, General Counsel
Texas Board of Nursing
333 Guadalupe, Suite 3-460
Austin, Texas 78701

Re: Review of Chapter 228. Pain Management, §228.1

The APRN Alliance is a partnership of Advanced Practice Registered Nurse (APRN) organizations, including the Consortium of Texas Certified Nurse-Midwives (CTCNM), Texas Association of Nurse Anesthetists (TxANA), Texas Clinical Nurse Specialists (TxCNS), Texas Nurse Practitioners (TNP), and Texas Nurses Association (TNA). Together, we represent the unified voice of nearly 20,000 APRNs in Texas.

As an informal collaborative, our focus is on promoting access to quality care by improving practice for all APRNs in Texas. That is why the APRN Alliance respectfully submits the following comments to Title 22 Texas Administrative Code §228.1, Pain Management (Rule Review published in the April 6, 2018 Texas Register).

While we feel strongly that this rule is necessary, we have some concerns about the language used. According to subsection (b), the rule sets forth standards for an Advanced Practice Registered Nurse (APRN) "who provides pain management services." This is extremely broad, as almost every APRN manages pain in their daily practice.

§228.1 tracks the language of the Texas Medical Board's (TMB's) §170.3 closely, with one major difference—nothing in §228.1 limits its applicability. Almost every subsection in §170.3 is limited by the word "chronic" before "pain." "In the case of chronic pain, the medical record must document…" in subsection (1), "(2) Treatment plan for chronic pain," "the use of controlled substances for the treatment of chronic pain" in (3), and so on.

While the lack of a limiting term may have been unintentional, we are concerned about the confusion it could cause for practitioners and their employers. We hope that the Board will take this opportunity to clarify this rule.

The other major concern is subsection (i). It states that an APRN who practices in a pain management clinic must verify the clinic's license, be available on site with the physician at least 33 percent of operating hours, and review 33 percent of patient charts, in accordance with §168.201, Occupations Code. However this is not what the Occupations Code says.

§168.201(c) says "*the owner or operator* of a pain management clinic shall: (1) be on-site at the clinic at least 33 percent of the clinic's total number of operating hours; and (2) review at least 33 percent of the total number of patient files of the clinic, including the patient files of a clinic employee or contractor…" According to §168.001, "Operator" means "an owner, medical director, or physician affiliated or associated with the pain management clinic in any capacity."

Further, §168.201(a), which does not relate to the on-site and chart review requirements, states "the owner or operator of a pain management clinic, *an employee of the clinic*, or a person with whom a clinic contracts…" In other words, subsection (a) shows that the legislature intended to delineate between owners and operators, employees, and contractors. Subsection (c) only applies to owners and operators.

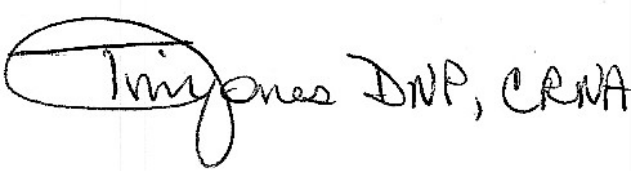
We ask that subsection (i) of §228.1 be amended so that it does not apply to APRNs who are employees. To ask every APRN employee to review 33 percent of all charts is unnecessary and not required by law.

Finally, if the Board is willing to make changes to the rule, it would be a good opportunity to alleviate some confusion with regards to §228.1(i), subsections (4) and (5), possibly by reversing their order.

We thank you for this opportunity to provide our expert perspective on the proposed changes to Title 22 Texas Administrative Code §228.1, Pain Management.

Sincerely,

Jeff Watson, DNP, RN-BC, NEA-BC, NE-BC, CRRN
President, Texas Nurses Association



Tim Jones, DNP, CRNA
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Robert Metzger, DNP, APRN, FNP-BC
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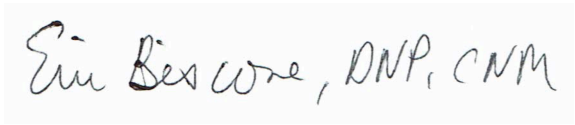

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