Agenda Item: 6.2
Board Meeting on October 25-26, 2018
Prepared by: Jena Abel

Consideration of Adoption of Proposed Amendments to 22 Tex. Admin. Code §222.8, relating to *Authority to Order and Prescribe Controlled Substances* and §222.10, relating to *Enforcement,* including Written Comments Received and Results of Public Hearing, if any

Background: Proposed amendments to §222.8 and §222.10 were approved by the Board at its July 2018 meeting for submission to the *Texas Register* for public comment. The proposal was published in the *Texas Register* on August 31, 2018, and the comment period ended on September 30, 2018. The Board received one written comment on the proposed amendments. The Board did not receive any requests for a public hearing. A copy of the written comment received is attached hereto as Attachment "A".

The Board received a comment from a representative of the APRN Alliance. Staff recommends making some of the commenter's suggested changes.

A summary of the comment received and Staff's proposed response is attached as Attachment "B". The proposed rule text, with recommended changes, is included in Attachment "C".

Board Action: Move to adopt the proposed amendments to 22 Texas Administrative Code §222.8, relating to *Authority to Order and Prescribe Controlled Substances* and §222.10, relating to *Enforcement*, with changes, as set forth in Attachment "C". Further, authorize Staff to publish the summary of comments and response to comments attached hereto as Attachment "B".

Attachment “B”

Summary of Comments Received

Summary of Comment: A commenter representing the APRN Alliance states that the proposal creates two disciplinable offenses: failing to check the prescription monitoring program (PMP) and failing to properly document the check. However, the commenter points out that the Health and Safety Code §481.0764 provides that a failure to check the PMP is grounds for disciplinary action, but there is no mention of documenting the check in the patient’s records. The commenter states that the APRN Alliance feels strongly that documentation should be encouraged and appreciates the Board’s efforts to do so. However, the commenter recommends that the Board consider alternative ways to encourage documentation, without making failure to do so disciplinable. The commenter suggests that the Board could modify the language in the rule by creating a safe harbor for documentation instead of requiring it. This would ensure that the Board is not forced to discipline a nurse who can prove, despite failing to document, that they complied with the applicable law by checking the PMP. If the Board feels that failure to document should be independently disciplinable, the commenter asks that the Board reconsider the standards it has set for the documentation. The commenter states that the standards inject subjectivity into the rules, and could be resolved by requiring only the documentation, as the requirement is stated in §222.10(a)(6).

Further, the commenter states that the Board’s repeated use of the term “prescription record” implies that documentation will be made within the PMP itself, rather than in the patient’s medical record. If this is the case, the commenter questions whether

the Board has done its due diligence to ensure that the PMP has the ability to include the Board's various requirements. However, if the Board intended "prescription record" to mean the medical record, the commenter asks that the Board change the rule language to reflect its intent.

Finally, the commenter asks the Board to include an effective date for the rule in the rule language. The commenter states that although the Board acknowledges, in the preamble for the rule, that it will become effective in September 2019, few, if any, nurses will see the rule preamble. The commenter states that this will create confusion for nurses, especially if the legislature modifies the statutory requirements during the legislative session. Further, the commenter states that the Administrative Procedure Act requires that the rule become effective 20 days after filing with the Secretary of State. The Government Code §2001.036(a)(1) provides that the only way to move the effective date past the 20-day standard is "if a later date is required by statute or specified in the rule." The commenter states that the effective date of House Bill 2561 is not required by statute, but is instead required by the effective date provisions of the bill, which do not become statute upon passage. Therefore, as currently drafted, the commenter states that a later date is not required by statute or specified in rule, and the rule will become effective 20 days after filing with the Secretary of State's Office. The commenter urges the Board to remedy this oversight by specifying an effective date in the rule.

Agency Response: The minimum standards of nursing practice require nurses to accurately and completely document the care they render. For APRNs who prescribe medications, this includes appropriate documentation of treatment plans and goals,

evaluation of treatment options, and rationale for ongoing medical treatment. The review of the PMP is a necessary and important part of formulating an appropriate treatment plan for a patient, particularly in circumstances where the PMP indicates the patient's history of multiple prescriptions from several different providers. Likewise, it is also important for a prescriber to document the rationale for prescribed medication(s) in order to ensure that the prescriber has appropriately considered the PMP, if applicable, and/or other pertinent factors that may affect the effectiveness and safety of the prescribed medications. These requirements are consistent with the prevailing standard of care and are intended to provide safeguards for patients and to prevent the inappropriate prescribing of dangerous and additive substances. To that end, the Board will review a prescriber's documentation when investigating complaints involving inappropriate or non-therapeutic prescribing. Further, a prescriber's failure to document the review of the PMP and/or the prescriber's rational for prescribing a controlled substance may result in disciplinary action, if warranted by the circumstances of the particular case. If the Board is unable to enforce the standards it prescribes, they are rendered meaningless. As such, the Board declines to make changes suggested by the commenter, as they relate to required documentation.

Further, the Board notes that §481.0765(c) exempts a prescriber from reviewing the PMP if the prescriber makes a good faith attempt to check the PMP, but is unable to access the information because of circumstances outside the control of the prescriber. The proposal gives the prescriber the benefit of this exception so long as the prescriber is able to document the circumstances that prevented him/her from reviewing the PMP. While the commenter states that this requirement is too subjective in nature, it seems

inevitable that every situation will necessarily involve unique circumstances that prevent a prescriber from accessing the PMP at the specific date and time he/she attempts to review the program. As such, this information, by its very nature, will be subjective and individualized. So long as the information is appropriately documented, the prescriber will not be subject to discipline for failing to review the PMP under these circumstances. The Board, therefore, declines to make changes to this portion of the rule, as requested by the commenter.

Although the proposal includes the same terminology as that of §481.0765, the Board has determined that clarification of the term "prescription record" is necessary within the context of this rule. House Bill 2561 amended the Health & Safety Code §481.0765 to require a prescriber to review the PMP prior to prescribing opioids, benzodiazepines, barbiturates, or carisoprodol. However, §481.0765(a) exempts a prescriber from this requirement if the prescription is for a patient who has been diagnosed with cancer or the patient is receiving hospice care and the prescriber clearly notes in the prescription record that the patient was diagnosed with cancer or is receiving hospice care. §481.0765(c) contains an additional exemption if a prescriber is unable to access the PMP due to circumstances outside of his/her control. HB 2561 utilizes the phrase "prescription record" in conjunction with requirements and conditions related to electronic prescription records. The bill does not utilize this term to refer to the PMP or to a patient's medical record. As such, the Board has determined that, in order to give proper effect to the exemptions in §481.0765, the rule should include reference to both electronic and non-electronic prescription records. To that end, the Board has changed the text of the rule as adopted to clarify that the exception(s) specified in §481.0765 must

be documented on either the patient's hard copy prescription or in the patient's electronic prescription record.

Finally, although the Board disagrees with the commenter that the effective date of a statute may not be utilized to satisfy the criteria set forth in the Government Code §2001.036(a)(1) without the necessity of the effective date appearing in the text of the statute itself, the Board has added the effective date of this rule into the text of the rule, as suggested by the commenter.

Attachment “C” (with recommended changes)

§222.8. Authority to Order and Prescribe Controlled Substances.

(d) Prescription Monitoring Program (PMP).

(1) APRNs should access and review the prescription monitoring program (PMP) authorized by Chapter 481, Health and Safety Code, prior to prescribing any controlled substance for patients being treated for pain.

(2) APRNs must access and review the PMP before prescribing opioids, benzodiazepines, barbiturates, or carisoprodol unless:

(A) the patient has been diagnosed with cancer or the patient is receiving hospice care; and

(B) the APRN clearly notes on the prescription or in the electronic prescription record that the patient was diagnosed with cancer or is receiving hospice care, as applicable.

(3) An APRN will not be subject to disciplinary action if the APRN:

(A) makes a good faith attempt to access and review the PMP prior to prescribing opioids, benzodiazepines, barbiturates, or carisoprodol, but is unable to access the information because of circumstances outside the control of the APRN; and

(B) clearly notes on the patient's prescription or in the patient’s electronic prescription record the APRN's attempt to access and review the PMP and the circumstances that prevented the APRN from being able to do so.

(4) Documentation that the review of the PMP occurred and rationale for prescribing a controlled substance must be included in the patient's medical record.

(5) This section takes effect September 1, 2019.

§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:

(6) failing to access and review the prescription monitoring program (PMP) authorized by Chapter 481, Health and Safety Code, before prescribing opioids, benzodiazepines, barbiturates, or carisoprodol, unless a statutory exemption contained in that chapter has been documented. If an APRN has made a good faith effort to comply with the requirement and is unable to do so because of circumstances beyond the APRN's control, documentation of this effort shall be made on the patient's prescription or in the patient's electronic prescription record.

(i) This section takes effect September 1, 2019.

APRN Alliance

TEXAS NURSES ASSOCIATION

TNP Texas Nurse Practitioners

TxANA Texas Association of Nurse Anesthetists

TxCNS

CTCNM Consortium of Texas Certified Nurse Midwives

September 24, 2018

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

Re: Prescription Monitoring Program (PMP) Rules

We appreciate the Board's implementation of the statutory PMP requirements put in place last session. However, the APRN alliance has two concerns with the rules as currently drafted. First, the rules appear to create a new disciplinary standard that is not supported by the statute. Second, the rules do not indicate that the law's effective date is September 1st, 2019.

Proposed Rules 222.8, 228.2, and 222.10 appear to create two disciplinable offenses: failing to check the PMP and failing to properly document the check. However, section 481.0764 of the Health and Safety Code provides that a failure to check the PMP is grounds for disciplinary action—there is no mention of documenting the check in the patient's records.

The APRN Alliance feels strongly that documentation should be encouraged, and we appreciate the Board's efforts to do so. However, we hope that the Board of Nursing will consider alternative ways to encourage documentation, without making failure to do so disciplinable. The Board could modify the language in 222.8(d), 222.10(a)(6), 228.2(c)(2), and 228.2(d) by creating a safe harbor for documentation instead of requiring it. This would ensure that the Board is not forced to discipline a nurse who can prove, despite failing to document, that they complied with the applicable law by checking the PMP.

If the Board feels that failure to document should be independently disciplinable, we ask that the Board reconsider the standards it has set for the documentation. For example, 228.2(c)(2) requires nurses to record "the circumstances that prevented the APRN from being able to" access the PMP. Likewise, subsection (d) states that nurses must record the "rationale for prescribing a controlled substance." These standards inject subjectivity into the rules, and could be resolved by requiring only the documentation, as the requirement is stated in 222.10(a)(6).

Additionally, the Board's repeated use of the term "prescription record" implies that documentation will be made within the PMP itself, rather than in the patient's medical record. If this is the case, we hope that the Board has done its due diligence to ensure that the PMP has the ability to include the Board's various requirements. However, if the Board intended "prescription record" to mean the medical record, we ask that the Board change the rule language to reflect their intent.

Finally, we ask the Board to include an effective date for this rule in the rule language. The Board acknowledges, in the preamble for these rules, that they will become effective in September 2019. But few, if any, nurses will see the rule preamble. This will create confusion for nurses, especially if the legislature modifies the statutory requirements during the legislative session.

Further, the Administrative Procedure Act requires that the rules become effective 20 days after filing with the secretary of state. Section 2001.036(a)(1), Government Code, provides that the only way to move the effective date past the 20-day standard is "if a later date is required by statute or specified in the rule." Unfortunately, the September 1, 2019, effective date is not required by statute—it is required by the effective date provisions of the bill, which do not become statute upon passage. Therefore, as currently drafted, a later date is not required by statute or specified in rule. We hope that the Board will remedy this oversight by specifying an effective date in the applicable rules.

Sincerely,

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President, Texas Nurses Association

Tim Jones, DNP, CRNA
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