Agenda Item: 6.4
Prepared by: C. Marshall & J. Sparks
April 2008

Adoption of Repeal of §§ 217.19 and 217.20, and adoption of New §§217.19 and 217.20, Relating to Incident-Based and Safe Harbor Peer Review

Proposed Revisions to Peer Review Rules 217.19 & 217.20

Summary of Request:

This agenda item is for review, discussion, and board action regarding comments received and response to comments relating to the re-proposed peer review rules [Tex. Reg. 2/15/08]. The repeal of the current rules 217.19 and 217.20 remains in effect in conjunction with this request.

Historical Perspective:

For an extensive historical perspective of peer review, please reference Agenda Item 6.8 in the January 2008 BON Board Meeting agenda. A brief summary of the key changes brought about by SB 993 and incorporated into re-proposed new peer review rules is also accessible at the following link (page 14, October 2007 BON Bulletin) ftp://www.bon.state.tx.us/oct07.pdf.

Due to extensive comments and recommendations made to the first proposed new peer review rules, during the January 2008 board meeting, the board approved several amendments, primarily to rule 217.20, and moved to re-propose the new peer review rules.

Rules 217.19 Incident-Based Peer Review and Whistleblower Protections and 217.20 Safe Harbor Peer Review and Whistleblower Protections were published in the February 15, 2008 issue of the *Texas Register*, Volume 33, Number 7, pp 1222-1232, http://www.sos.state.tx.us/texreg/. The 30-day comment period ended March 17, 2008. Two comments were received: one negative, and one in support of the re-proposed rules.(see Attachment A).

Pros & Cons:

Pros: Adoption of new peer review rules 217.19 and 217.20 as re-proposed will provide necessary guidance to nurses and peer review committees throughout the State in revising their nursing peer review policies and processes to comply with statute and rules of the BON.

Cons: Since provisions of SB993 became effective 9/1/07, failure to adopt and publish new peer review rules may result in confusion, and possible lack of compliance with the new statutes due to a disconnect between the current peer review rules and the new statutes.

Staff Recommendations:

Move to adopt the repeal of current nursing peer review rules 217.19 and 217.20, and to adopt the re-proposed nursing peer review rules:

- 217.19 Incident-Based Nursing Peer Review and Whistleblower Protections; and
- 217.20 Safe Harbor Peer Review for Nurses and Whistleblower Protections.

Further move to publish these adopted new rules in the *Texas Register*. The board authorizes staff legal counsel to make non-substantive or grammatical changes in the proposed new rules for clarification and format consistency.

Comments Received and BON Response to Comments
Relating to Re-Proposed Nursing Peer Review Rules 217.19 and 217.20
April 2008

(1) **§ 217.19(a) and § 217.20(a):** Commenter asked if the list of committees contained within the definition of "Patient Safety Committee" (in both rules) was intended to be exclusive with regard to the specified entities, or if the intent was "including but not limited to"? An additional concern/comment added to this question was that "permitting a hospital to completely control a patient safety committee is tantamount to a self evaluation which is completely subjective; the likelihood of a self report to a licensing or accrediting body is unlikely."

Staff Response: In both rules, definition (*10) Patient Safety Committee*, (A) and (B) come straight from the statute language in §303.0075 of the Nursing Peer Review Law (NPR). The Nursing Practice Advisory Committee (NPAC) added proposed language in (C) to include provision for *"a multi-disciplinary team that includes nursing representation "or any committee established by the same entity to promote best practices and patient safety, may apply as appropriate."*

A number of national patient safety organizations have promoted the utilization of multi-disciplinary teams to remedy system breakdowns relating to patient safety initiative for several years. Examples include the Institute of Safe Medication Practices, http://www.ismp.org. , the Agency for Healthcare Research and Quality, http://www.ahrq.gov/, and the Joint Commission, http://www.jointcommission.org/.

Staff believe the NPAC proposed language in (C) makes it clear that there is no limitation strictly to the entities listed in the definition. The term "patient safety committee" itself is seen as a generic term used legislatively since it would be impossible to know the names of every committee active within a given setting to investigate error events and recommend changes appropriate to the setting.

The BON does not regulate hospitals or practice settings of any kind; therefore, the BON has no authority to mandate who "controls the patient safety committee." The BON's jurisdiction extends up to the Chief Nursing Officer (CNO), nurse administrator, or top nursing position by any other title. A CNO, nurse administrator or other nurse in a similar nursing leadership position can be reported to the BON and investigated for failing to assure that peer review processes are conducted in good faith. This same comment was received and responded to during the January 2008 Board meeting. Recommend no changes to proposed rule language.

(2) **§ 217.19(a)(10) and § 217.20(a)(10)**: Commenter states that "Whistleblower protections need to be strengthened; penalties for a hospitals' refusal to give a nurse safe harbor peer review (beyond reporting the DON or CNE to the BON) should be considered. Otherwise, the Board will be inundated with complaints that an already overburdened staff would have to deal with."

Staff Response: As noted in the BON response to #1, the BON does not regulate hospitals or practice settings of any kind; therefore, the BON has no authority to propose sanctions on a facility, agency, or other employer of nurses. The NPA also prohibits board members and staff from lobbying the Texas Legislature regarding bills that would amend the parts of the Texas Occupations Code relating to the practice of nursing. Nurses are encouraged to work through their professional organizations, as these organizations can lobby the Legislature for bills that can impact work setting and employment issues for nurses. This same comment was received and responded to during the January 2008 Board meeting. The BON does not have the authority to amend the rules as suggested in this comment. Recommend no changes to proposed rule language.

(3) **217.19(a)(5), 217.20(a)(5):** Commenter states concern for the language in the BON's definition of "duty to a patient" regarding the phrase *"and to avoid engaging in unprofessional conduct (217.12 of this title)."* Commenter states that "Notwithstanding the fact that the Nurse Practice

Act (Tex. Occ. Code §301.352) specifically addresses refusal of unsafe assignments, the proposed language arguably dilutes the statute by Rule, conjoining the 217.11 obligations with an unprofessional conduct requirement."

Staff Response: BON staff believe the above perception of the proposed rule language is inaccurate. In both incident-based and safe harbor situations, a nursing peer review committee could find that they are dealing with a situation where either a nurse has knowingly engaged in unprofessional conduct (such as stealing from a patient), or where a nurse has invoked safe harbor because he/she was directed to engage in unprofessional conduct (such as falsifying a patient's medical record). The BON expects a nurse to avoid engaging in conduct that could cause harm to the patient. Staff further believe the distinction of when a nurse would be justified in refusing an assignment is sufficiently addressed in §217.20(g).

Recommend no changes to proposed rule language.

(4) **217.20(g):** Commenter states concern that this section "essentially requires that the nurse take the assignment and artificially limits her ability to refuse in accordance with the statute Tex. Occ. Code 310.352 and with 217.11(1)(T)." A further comment on this topic speaks to the lack of a definition for "unjustifiable risk of harm" in relation to the nurse's duty to maintain client safety when considering a nursing assignment–and concern that rule language "obscures" the findings of a landmark court case "Lunsford vs. BNE" (page 3, paragraph 5).

Staff Response: NPAC suggested language in §217.20(g) provides clarification for what the BON considers to be "good faith" reasons for refusing to engage in requested conduct or an assignment. BON staff believe this language is important to differentiate and provide guidance to nurses with regard to when it is appropriate to refuse versus to accept the first offered assignment when invoking safe harbor.

Take the situation in which a nurse had her license sanctioned by the BON for invoking Safe Harbor in "bad faith" and not only refusing to engage in conduct, but leaving the facility. In this instance, neither the acuity or number of patients assigned on the nurse's home unit exceeded levels routinely handled by nurses in the practice setting. Despite the nursing supervisor obtaining additional staff, the nurse refused the assignment and left the premises, leaving nursing colleagues who were tired after working for 12 hours, to continue caring for expectant mothers and their unborn infants.

Applying the above example to the proposed rule section in question, section 217.20(g)(2)(A) would require the nurse refusing the assignment to "...collaborate in an attempt to identify an acceptable assignment that is within the nurse's scope and enhances the delivery of safe patient care." The rule does not mandate the nurse accept an assignment— but rather directs that the nurse must at least communicate his/her concerns with the supervisor, and that the supervisor, in turn, must try to address the issue—both nurses acting in the best interest of patient safety [rule 217.11(1)(B)]. In other words, simply handing the safe harbor form to the supervisor and walking out is not acceptable or considered acting in "good faith."

What constitutes "unjustifiable risk of harm" cannot be defined in rule as it will vary in every practice setting and situation. This highlights the premise of safe harbor to have a peer review committee of nurses from the practice setting in question review the conduct requested when a nurse invokes safe harbor. Who better than other nurses from the same practice setting to make an accurate determination of the nurse's "duty" and what would constitute "unjustifiable risk of harm"? A nursing peer review committee must consider the nurse's duty under 217.11(1)(B), which is further described in relation to the *Lunsford vs. BNE* landmark case in Board Position Statement 15.14, Duty of a Nurse in Any Setting, at http://www.bon.state.tx.us/practice/position.html#15.14.

In addition, the comments received demonstrate the risks of taking part of a board rule [aka, 217.20(j)(4)] out of context. Subsections 217.20(j)(4)(A)-(D) clarify that even if a CNO/nurse administrator disagrees with the determination of the peer review committee, this does not

nullify the nurse's protections from employer retaliation set forth in NPR Law 303.005(c) relating to either a nurse's refusal to engage in certain conduct under Nursing Practice Act (NPA) §301.352, or for requesting a Safe Harbor Peer Review determination. The subsections further list required actions of the CNO if he/she takes action not supported by the peer review committee's findings.

Additionally, NPA statutes in §301.405(b) and §301.403 clearly indicate separate reporting requirements for peer review and the nurse's employer. Given the multitude of sections in the statute and proposed rules, including 217.20(j)(4)(D), that prohibit employer retaliation, the only reason a CNO or nurse administrator could differ with the safe harbor peer review committee's findings would be if he/she believed the nurse did not invoke safe harbor in good faith, in which case a report to the board would be required under rule 217.11(1)(K) and potentially §301.405(b) depending upon the employment action taken.

Recommend no changes to proposed rule language.

(5) Commenter states that "Safe Harbor is no protection for loss of license, employment, or civil liability." Further statements address concerns for rule language regarding peer review committee determinations being non-binding if the CNO or nurse administrator believe in good faith that the committee has incorrectly determined a nurse's duty (page 3-4, paragraph 6).

Staff Response: First, language regarding the decision of peer review being non-binding on the CNO or nurse administrator has been in statute §303.005(d) for many years as well as in the current Safe Harbor §217.20 (2003). The BON cannot change or ignore statute.

The statute in NPA §301.352, mentioned earlier in the commenter's letter, does provide a nurse with civil recourse should the nurse's employer engage in retaliatory action with regard to the nurse's employment for invoking Safe Harbor or refusing to engage in conduct that violates the statutes or board rules. SB 993 (the same bill that initiated the current proposed changes to the peer review rules) did strengthen a nurse's protection from employer retaliation. Current NPA §301.413, and NPR Law §§303.005(c), (d), and (h), along with proposed rule §§217.20(e)(2)-(3), and (i)(3) address the prohibition of retaliatory action by an employer against the nurse who either invokes safe harbor or refuses in good faith to engage in conduct that the nurse believes could violate his/her duty to a patient. As the BON does not regulate employment issues or practice settings, the BON has no authority to impose any penalty on an employer. This is, and always has been, a private civil matter for the nurse to pursue.

As for civil liability protection for the nurse, this also is and always has been beyond the authority of the BON's regulations. The language in the new rules does not, and cannot, impact civil liability.

With regard to Commenter's statement that "safe harbor is no protection for loss of license," this is factually incorrect. Both past and current statutes and rules on Safe Harbor have provided the nurse protection against BON licensure sanctions, including revocation, provided the nurse invoked Safe Harbor in good faith. The BON would be lax in its mission to protect the public if it approved rule language that unequivocally exonerated a nurse for refusing an assignment without regard to the nurse's intent to engage in unprofessional conduct versus upholding his/her duty to the patient. In addition, board statutes and rules relating to procedural due process with regard to investigation of alleged violations of the NPA and board rules further provide a nurse the opportunity to demonstrate good faith efforts to comply with BON statutes and rules. Recommend no changes to proposed rule language.

ATTACHMENT A

COMMENTS RECEIVED ON RE-PROPOSED PEER REVIEW RULES

TEXAS NURSES ASSOCIATION

DELIVERED VIA EMAIL TO:
joy.sparks@bon.state.tx.us

March 14, 2008

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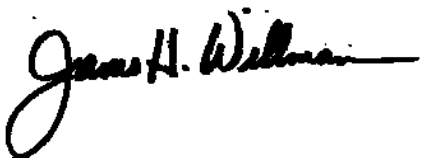
Re: Proposed Rules 217.19 (Incident-Based Nursing Peer Review) and 217.20 (Safe Harbor Nursing Peer Review); 33 Tex Reg 1222 (2/15/2008)

Dear Ms. Sparks:

The Texas Nurses Association supports adoption of the board's proposed Rules 217.19 (Incident-Based Nursing Peer Review) and 217.20 (Safe Harbor Nursing Peer Review) as published in the Texas Register at 33 Tex Reg 1222. Again, TNA wishes to express its appreciation to the board and its staff for the work done on revising these two rules.

Respectfully submitted,



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March 14, 2008

Via Facsimile 305-8101
and Electronic Mail
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Dear Joy,

Please accept my comments to Proposed Rules for Safe Harbor and Incident Based Peer Review. I am privileged to represent nurses in this State who have been retaliated against for following these Rules and advocating for their patients. I now have five active lawsuits and have seven more nurses ready to file suit; the nurses in these cases either refused unsafe assignments or reported violation of law, mostly related to unsafe staffing. For these nurses and the countless others who have no idea what their rights are, I implore Staff to hold a public hearing on these Rules before adoption to ensure that the public is truly protected. The nurse cannot protect her patient if she is not empowered to challenge unsafe conditions.

My comments are as follows:

Proposed 217.19 (a); 217.20 (a)

(10) Patient Safety Committee: Any committee established by an association, school, agency, health care facility, or other organization to address issues relating to patient safety that includes:

(A) the entity's medical staff…

(B) a medical committee…or

(C) A multi-disciplinary committee, including nursing representation, or any committee established or contracted within the same entity to promote best practices and patient safety, may apply as appropriate."

Is the list intended to be exclusive with regard to the specified entities, or do you mean "including but not limited to" ? The old adage about the "fox guarding the henhouse" is

applicable here. Allowing a hospital to completely control a patient safety committee is tantamount to a self evaluation which is completely subjective; the likelihood of a self report to a licensing or accrediting body is unlikely. Rules such as HIPAA and the Texas Health & Safety Code provisions protect the health information of any consumer whose health information would be considered negate any challenge that a hospital would make about breach of confidentiality.

Whistleblower protections need to be strengthened; penalties for a hospital's refusal to give a nurse safe harbor peer review (beyond reporting the DON or CNE to the Board of Nursing) should be considered. Otherwise, the Board will be inundated with complaints that an already overburdened staff would have to deal with.

Proposed 217.19(a)(5), 217.20(a)(5)

The BON proposed the following rules: (217.19(a)(5), 217.20(a)(5)) on" "duty to a patient" stating that "Duty to a patient--A nurse's duty is to always advocate for patient safety, including any nursing action necessary to comply with the standards of nursing practice (217.11 of this title) and to avoid engaging in unprofessional conduct (217.12 of this title). This includes administrative decisions directly affecting a nurse's ability to comply with that duty. "

My concern here is that this language "and to avoid" ignores the nurse's primary duty under 217.11(1)(S) Standards of Nursing Practice to Accept only those nursing assignments that take into consideration client safety and that are commensurate with the nurse's educational preparation, experience, knowledge, and physical and emotional ability."

Notwithstanding the fact that the Nurse Practice Act (Tex. Occ.Code 301.352) specifically addresses refusal of unsafe assignments, the proposed language arguably dilutes the statute by Rule, conjoining the 217.11 obligations with an unprofessional conduct requirement.

Proposed 217.20(g)

Further, I am concerned that the proposed Rules essentially require that the nurse take the assignment and artificially limits her ability to refuse in accordance with the statute Tex. Occ. Code 310.352 and with 217.11(1) (T).

Specifically, **proposed 217.20(g)** states: " A nurse invoking safe harbor may engage in the requested conduct or assignment while awaiting peer review determination unless the conduct or assignment is one in which: (A) the nurse lacks the basic knowledge, skills, and abilities that would be necessary to render the care or engage in the conduct requested or assigned at a minimally competent level such that engaging in the

requested conduct or assignment would expose one or more patients to an unjustifiable risk of harm; or (B) the requested conduct or assignment would constitute unprofessional conduct and/or criminal conduct such as fraud, theft, patient abuse, exploitation, or falsification." The proposed Rule does speak to refusal,

but unreasonably limits the ability to refuse: "(2) If a nurse refuses to engage in the conduct or assignment because it is beyond the nurse's scope as described under paragraph (1)(A) of this subsection: (A) the nurse and supervisor must collaborate in an attempt to identify an acceptable assignment that is within the nurse's scope and enhances the delivery of safe patient care; and (B) the results of this collaborative effort must be documented in writing and maintained in peer review records by the chair of the peer review committee."

This change echoes the opinion of the Texas Nurses Association (TNA) who disagrees with nurses refusing unsafe assignments. In previous public comments TNA stated: "Safe Harbor provides a mechanism to resolve good faith disagreements "about what is a nurse's duty to a patient in a specific situation. TNA believes that normally it is In the best interest of the patient and also the nurse for the nurse to engage in the conduct or assignment awaiting nursing peer review.... While patient safety is more likely to be better promoted by the nurse's engaging in the conduct or assignment "

Malarkey! The hospital or facility alone bears the burden of employing adequate staff; they advertise to the public and charge for the care. If nurses are put in the position of “taking the assignment anyway” how will patients be protected? People go to the hospital mainly to get NURSING CARE, and if nurses keep accepting the assignments under Safe Harbor, who benefits?

There is a major problem with this flawed thinking. In this instance, the direct care RN is required to engage in the conduct mandated by her/his supervisor and violate her duty to her patient unless there is a risk of "unjustifiable harm". When evaluating the duty of nurse to protect her patient from risk of harm, there is no "justifiable risk" of harm. The RN has an independent duty to her/his patient <u>regardless</u> of what the supervisor or employer thinks her/his duty is. The Rule minimizes and obscures a key finding of a precedent-setting lawsuit called the Lunsford case stating that the RN's duty is to the patient even if it means going against the agency’s policies. Note that the Board does not define justifiable risk anywhere in the proposed rules.

Furthermore, Safe Harbor is no protection for loss of license, employment or civil liability. The proposed Rule also specifies that the CNO has the ultimate decision making authority with regard to the determination of duty when an assignment is refused: "(4) If a nurse requests a Safe Harbor Peer Review determination under TOC ?303.005(b) and refuses to engage in the requested conduct or assignment pending the safe harbor peer review, the determinations of the committee are not binding if the CNO

or nurse administrator believes in good faith that the committee has incorrectly determined a nurse's duty." The Peer Review committee in a Safe Harbor refusal scenario is a "kangaroo court" who can be overruled if the CNO or supervisor does not agree with the Committee's determination of the nurse's duty (217.20(j)(4). Imagine a scenario where a CNO would agree with a refusal. I have not seen it yet and Safe Harbor has been alive (but unwell) for many years now.

Whistleblower protections need to be strengthened; penalties for a hospital's refusal to give a nurse safe harbor peer review (beyond reporting the DON or CNE to the Board of Nursing) should be considered. Otherwise, the Board will be inundated with complaints that an already overburdened staff would have to deal with.

Respectfully submitted,

Elizabeth L. Higginbotham, RN, J.D.

ELH/lkm