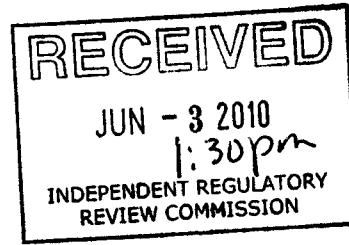




THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

2846



June 1, 2010

Ann Steffanic, Board Administrator
Pennsylvania State Board of Nursing
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: 16A-5122: IV Therapy Functions for Licensed Practical Nurses—Proposed Regulations

Dear Ms. Steffanic:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its members, more than 225 acute and specialty hospitals and health systems, appreciates the opportunity to comment on the State Board of Nursing’s (Board) proposed regulations related to the role of the licensed practical nurse (LPN) with respect to intravenous therapy.

HAP reviewed the proposed regulations with nurse leaders from various work settings including acute care, medical rehabilitation, home health, and long-term care. Our comments reflect the feedback we received from these nurse leaders with respect to the proposed rule.

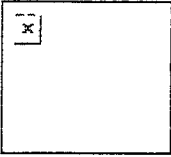
HAP supports the efforts the Board has taken to address the LPN’s role in IV therapy to ensure patient safety and the provision of quality care. HAP also appreciates the efforts the Board had taken to engage the appropriate stakeholders in a review of pre-draft regulations. HAP recognizes that the Board incorporated many of HAP’s recommendations from the pre-draft regulations into the published proposed regulations. Based upon the discussions that HAP has had with nurse leaders utilizing LPNs in the above referenced care settings, HAP would like to offer the following comments and/or recommendations to further improve or clarify the proposed regulations:

§21.141. Definitions

- Reconsider use of the term Focused Assessment—HAP received many comments regarding this definition. Across all the settings referenced above, there was concern about the use of the term focused assessment. There was repeated concern expressed about introducing the term assessment as part of the LPN’s scope of practice, with many nurse leaders indicating that the LPN Practice Act does not allow for assessment. HAP understands that the State Board of Nursing is attempting to recognize the vital role that LPNs play in situational awareness. Lacking situational awareness has been identified as one of the primary factors in medical errors. It is not necessary to introduce the term functional assessment to recognize the role that LPNs play in situational awareness.

Although the State Board of Nursing defines functional assessment, the term is only used once in the proposed regulations at §21.145(f) (3), which when removed from the proposed language, does not substantively change how the LPN is expected to practice. Additionally, in the section





preceding this, §21.145(f) (2), the Board uses the term assessment, which is squarely the purview of the licensed professional registered nurse (RN).

HAP recommends that the term focused assessment be removed from the proposed regulations. HAP recommends that the Board recognize that the LPN contributes to situational assessment through their knowledge, experience, competency, patient monitoring, and sharing of patient data and observations with the professional registered nurse.

- Add definition of Venous Access Device—HAP appreciates the inclusion of the definitions of the various types of intravenous catheters; however, HAP recommends the inclusion of the term venous access device since the term is used in §21.145(g). It should be clear that when using this term that the Board has determined that the LPN can perform certain IV therapy functions regardless of whether the device is a centrally or peripherally inserted line.

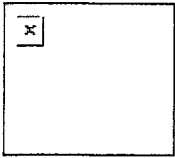
Venous Access Device — any centrally or peripherally inserted catheter used for the purpose of intravenous infusion therapy.

- Provide examples of electronic communication and add definition of assistance readily available—in §21.145(f) (4) it states that “*If supervision is provided by electronic communication, the LPN shall have access to assistance readily available.*” In discussion with nurse leaders, it was evident that there would be circumstances where the LPN would not have immediate physical access to an RN. This may be in the home setting where it could take up to an hour for an RN to be available depending on the geography of the area or in a nursing home depending on the number of patients in the nursing home. There was concern that if the LPN were caring for patients with central lines, that this lack of immediate access to the RN would not be safe.

For example, nursing home facility regulations 028 Pa. Code, §211.12. Nursing Services (f) (1) and (f) (2) outline the minimum staffing ratios by shift for nursing homes based on census: “When the facility designates an LPN as a nurse who is responsible for overseeing total nursing activities within the facility on the night tour of duty in facilities with a census of 59 or under, a registered nurse shall be on call and located within a 30-minute drive of the facility.”

HAP is requesting that the State Board of Nursing provide some additional clarification about what the expectations would be with regard to electronic supervision and having “assistance readily available” particularly in situations where the LPN is caring for patients with central lines and the RN may not be able to physically be at the facility or patient’s home for up to 30 minutes or more.

- Add definition of Maintenance—in §21.145(g) (5) it states that an LPN may perform certain IV therapy functions, including the performance of maintenance. When HAP asked nurse leaders what they considered to be IV maintenance, many responses were offered, including dressing changes, IV tubing changes, observing for redness or swelling at the site, and saline or heparin



flushes. Furthermore, there seemed to be some overlap between what is considered site care and maintenance. HAP recommends that the State Board of Nursing clarify what is meant by maintenance and site care, especially if there are different expectations between what can be performed with respect to central lines versus peripheral lines.

- Add definition of Therapeutic Phlebotomy—in §21.145a. (14), the proposed regulations state that an LPN is prohibited from performing therapeutic phlebotomy. There was discussion about what therapeutic phlebotomy meant. HAP suggests defining therapeutic phlebotomy as part of the regulations.

Therapeutic Phlebotomy—Therapeutic phlebotomy (therapeutic bleeding) is a controlled removal of a large volume (usually a pint or more) of blood. It is used mainly to reduce blood volume, red cell mass, and iron stores. Therapeutic phlebotomy may be indicated for hemochromatosis, polycythemia vera, porphyria cutanea tarda, and polycythemia secondary to A-V fistulae, cyanotic congenital heart disease or cor pulmonale.

§21.145. Functions of the LPN

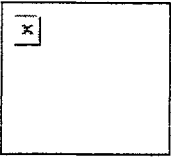
§21.145(f)

- Modify language in §21.145(f) (2)—concern was expressed during discussions HAP had with nurse leaders across all settings with regard to the use of the term “assess” in this section as it is associated with the role of the RN and not the LPN. Additionally, HAP believes that many of the items listed should be assessed by the licensed professional nurse before making the patient assignment and should be discussed with the LPN before the LPN initiates the IV therapy.

HAP recommends that this section be revised to read:

(2) Prior to the initiation of IV therapy, the LPN under the supervision, direction, and collaboration with the supervising professional shall:

- (i) verify the order and identity of the patient;*
 - (ii) review and check for any patient allergies, fluid, or medication contraindications;*
 - (iii) discuss any special considerations related to the patient’s circulatory status and infusion site;*
 - (iv) review the equipment that will be used to assist in intravenous infusion; and*
 - (v) discuss what instructions the patient should be given, especially related to what kinds of symptoms or issues related to the intravenous therapy should be reported to nursing staff.*
- Modify language in §21.145(f) (3)—as stated previously, HAP recommends that the State Board of Nursing remove the term “focused assessment” from the regulations. HAP believes that the essence of the requirements in this provision is not substantively changed by deleting this term.



HAP recommends that this section be revised to read:

“Maintenance of IV therapy by an LPN must include ongoing observation of the patient, monitoring the IV site, and maintaining the equipment.”

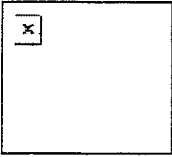
- Eliminate §21.145(f) (5) (i)—HAP believes an LPN should never be assigned to a patient whose condition is critical, fluctuating, unstable or unpredictable and strongly recommends that this statement be removed from the regulations.

§21.145(g)

As a general statement, there seemed to be some confusion about whether or not an LPN could perform all of the outlined tasks and procedures with all types of venous access devices. **The Board needs to make clear which of these tasks and procedures relates to all venous access devices and which do not because there seemed to be confusion among those reading and discussing the regulations with HAP.**

A reoccurring concern was raised with regard to the LPN’s role as it relates to central venous lines. Nurse leaders were apprehensive about allowing the LPN to perform IV therapy related to central venous lines, particularly given the intense scrutiny around central line-associated bloodstream infections and the potential risk to the patient if not managed correctly. However, nurse leaders also recognized the changing health care delivery system and the need to have LPNs care for patients with PICC lines in alternate care settings. Nurse leaders also questioned whether any evidence existed to support the formal expansion of the LPN scope of practice as it relates to LPNs and central venous catheters. The following represent some of the concerns that were brought to HAP’s attention by nurse leaders.

- LPNs have been doing IV therapy for awhile; however, I think that where central venous catheters are concerned, RNs should be working with those devices, mainly because they enter into the subclavian vein, a much more direct route into a person’s circulatory system.
- Letting LPNs perform what is proposed regarding central venous lines lessens the differentiation between what a registered nurse versus licensed practical nurse can do. Before embarking on these changes, it would be important to understand what, if any, issues this presents with respect to the potential for serious complications with central lines based on the data and evidence.
- The proposed changes to the curriculum are admirable, but I would advocate for re-enforcing these educational objectives for the RNs working in the settings where LPNs are being targeted. My experience with RNs in long-term care facilities, for example, is that they often have little exposure or comfort level with IV therapy. This makes the precaution of referring LPNs to their RN counterparts, for “guidance when the patient’s care needs exceed the licensed practical nursing scope of practice; the patient’s care needs surpass the LPN’s knowledge, skill or ability; and the patient’s condition deteriorates or there is a significant change in condition, the patient



is not responding to therapy, the patient becomes unstable or the patient needs immediate assistance” unrealistic in the long-term care setting.

- At a time when patient safety is a highly publicized issue, with reverberations in the customer satisfaction, reimbursement, and compliance arenas, the Board is proposing changes to lessen rather than strengthen the credentials of those administering potentially risky therapies to patients. In the home setting, where there is generally only one patient, and oftentimes only one medication to be administered, the risk for error is limited. In the institutional setting, however, there are multiple patients, often multiple therapies, as well as additional opportunities for confusion—feeding tubes, drains, etc., that have been involved in errors with adverse consequences. The requirement for pre-assessment of patients to determine that their condition is “stable and predictable,” the need to have an RN available for guidance, and the list of prohibitions makes use of the LPN for IV therapy in the home untenable.

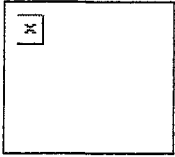
HAP would appreciate a formal evaluation of the literature to help understand what if any studies have been done to evaluate patient care outcomes associated with LPNs and IV therapy, particularly with central lines.

The following represent additional recommendations made by nurse leaders relating to §21.145(g).

- Clarify “initiation of appropriate interventions”—in §21.145(g) (2) it states that an LPN may perform the following IV therapy function: observation and reporting of subjective and objective signs of adverse reactions to any IV administration and initiation of appropriate interventions. During HAP’s discussion with nurse leaders, they asked the Board to consider identifying what those appropriate interventions might be for an LPN, particularly related to a central venous catheter.
- Modify language in §21.145(g) (4)—in this section, it states that an LPN may perform certain IV therapy functions, including the performance of site care. HAP believes that there needs to be an observation of the IV site before site care is performed and therefore recommends that §21.145(g) (4) be revised to read, “*observation of the intravenous insertion site and performance of insertion site care.*”
- Correct typo in §21.145(g) (10)—in this section, it states that an LPN may perform administration of solutions to maintain potency of an IV access device. HAP believes the Board meant to use the term “*patency*” in this section.

HAP further recommends that the Board revisit the provision in this section to enhance clarity. HAP would recommend that the administration of solutions to maintain patency of an IV access device only include the use of saline or heparin flushes. Therefore, HAP recommends that the term “*via direct push or bolus route*” be removed and this section be revised to read:

“Administration of solutions to maintain patency of an IV access device with saline or heparin flush.”



- Removal of §21.145(g) (13)—in HAP’s discussion with nurse leaders, none of them believed that it was good practice to collect blood specimens from any intravenous access device because of concerns with introducing infection and causing septicemia. Multiple comments were made that evidence does not support the collection of lab specimens from an IV access device. In light of this, HAP recommends that §21.145(g) (13) be removed from the regulations.

§21.145a. Prohibited Acts.

- Clarification with regard to blood, blood components and plasma volume expanders—nurse leaders recommended that the Board clarify that LPNs may not accept orders for blood and blood components within their current scope of practice. Therefore, HAP recommends that the first bullet under this section be revised to read as follows:

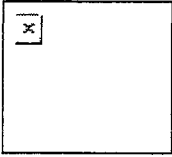
*“**May not take orders for or initiate administration of blood, blood components and plasma volume expanders.**”*

- Based on our discussion with nurse leaders, HAP recommends that §21.145a. (15) be amended to read, **“Access or deaccess implanted central venous catheters.”**

§21.145b. IV Therapy Curriculum Requirements

HAP supports the adoption of a standardized course curriculum such that the course could be provided as part of a licensed practical nurse education program or outside of such a program. There was widespread support for the proposed curriculum content; however, the following represent questions or recommendations for considerations by the Board.

- Recommended Number of Hours and Instructor Qualifications—while there was widespread support for the proposed course content, there was concern expressed about making sure that offered courses were adequate in length to ensure that the content was covered sufficiently to ensure sound practice. Additionally, clinical observation of practice, supervised lab instruction, and return demonstration were recommended for inclusion in the course. Nurse leaders thought that it would be helpful to have established minimum parameters for what the length of the course should be, including some establishment of clinical, laboratory, and didactic hours. HAP recommends that the Board provide minimum instructor qualifications for individuals who will be teaching the course. If the Board intends not to formally approve the courses offered by various groups, then employers believed that it would be helpful to have some minimum standards established in order to evaluate what education and training an LPN received in intravenous therapy upon hire to their organization.
- Inclusion of Lab Practicum—HAP believes that there should be a clinical component included in the IV therapy curriculum to ensure that the LPN has mastered the appropriate skills to assist



in IV therapy. Therefore, HAP recommends the inclusion of a lab practicum in the curriculum requirements.

- Approval of Courses—HAP questions whether the SBN will approve LPN IV therapy courses or whether the Board will depend on other established groups to review and approve the courses. If the latter is the case, what groups will the Board recognize as having the expertise and legitimacy to approve an LPN IV therapy course?
- LPNs Currently Certified in IV Therapy—HAP recommends that the Board clarify whether LPNs currently performing IV therapy would be required to complete an entire course in IV therapy or only selected portions of the redefined curriculum.
- Demonstration of Continued Competency—with the idea that IV therapy requires a set of specialized skills, HAP believes that the LPN should be required to demonstrate continued competency to perform the skills they obtained through the completion of the curriculum and for the maintenance of their IV therapy certification. Therefore, HAP recommends that language should be included in the regulations that would require the LPN to demonstrate continued competency in accordance with facility requirements.
- LPN Continuing Education—with the expansion of the role of LPNs and also considering that RNs are currently required to complete 30 hours of continuing education (CE) for re-licensure, HAP suggests that there should be some consideration by the legislature to also require CEs for LPNs. HAP suggests that the Board begin discussions through their legislative liaison to introduce LPN CE legislation.

HAP appreciates the opportunity to provide comments on these proposed regulations. If you have any questions about HAP's comments, please feel free to contact Mary Marshall, director, workforce and professional services at (717) 561-5312 or by email at mmarshall@haponline.org or me at (717) 561-5308 or by email at lgleighton@haponline.org.

Sincerely,

Lynn G. Leighton
Vice President, Health Services