# Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

*INDEPENDENT REGULATORY REVIEW COMMISSION*



(1) Agency: Department of State
**Department of State, Bureau of Professional and Occupational Affairs, State Board of Nursing**

(2) Agency Number: **16A**

Identification Number: **5122**

IRRC Number: 2840



(3) PA Code Cite: **49 Pa. Code §§ 21.141, 21.145, 21.145a, 21.145b, 21.203**

(4) Short Title: **LPN/IV Therapy**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Carole Clarke Smith, Senior Counsel, P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251) cclarke-sm@pa.gov.**

Secondary Contact: **Cynthia Montgomery, Regulatory Counsel, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251) cymontgome@pa.gov.**

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- X Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

**The regulation provides guidance to LPNs and other health care practitioners of the authorized scope of practice for LPNs related to IV therapy procedures. In addition, the regulation updates existing provisions regarding the education and training LPNs must complete before providing IV therapy functions.**

(8) State the statutory authority for the regulation. Include specific statutory citation.

**Section 17.6 of the Practical Nurse Law, 63 P.S. §667.6, authorizes the Board to establish rules and regulations for the practice of practical nursing.**

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

**The regulation is not mandated by any federal or state law or court order, or federal regulation. There are no relevant court decisions.**

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

**IV access devices are frequently used in health care and home health settings. In addition, many more patients are being transferred to long-term care facilities with more complex IV access devices. Public safety demands that LPNs working with these devices have the appropriate education, training, competency and supervision to do so safely. Health care facilities and consumers will benefit by having trained LPNs performing IV therapy. LPNs benefit by being able to contribute more to the health care team. The public benefits from having the lower cost LPNs perform this function. There are 57,760 actively licensed LPNs in Pennsylvania.**

(11) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

**Data is not the basis for this regulation.**

(12) Describe who and how many people will be adversely affected by the regulation. How are they affected?

**The Board has not identified any particular groups that will be adversely affected by the regulation.**

(13) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

**The 57,760 actively licensed LPNs in the Commonwealth who want to engage in IV therapy will be required to comply. The 75 approved LPN programs must comply with the curriculum requirements. There are currently 161 approved stand alone IV therapy courses. These programs will have to comply with the curriculum requirements as well as any programs approved after the regulation is effective.**

(14) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

**There will be a cost to LPNs who elect to take an IV therapy course if the course was not included in their educational program. As program costs vary (and program costs are not provided to the Board) it is difficult to estimate.**

(15) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

**There are no costs or savings to local government for complying with the regulation.**

(16) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

**There should be no additional costs to state government to comply with this regulation as the Board already approves IV therapy courses. However, a fee has never been charged for approval. If the Board determines that it is necessary to charge a fee, then the Board will obtain a fee report to quantify the costs of program approval and introduce a regulation package with that fee.**

(17) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

| | Current FY Year | FY +1 Year | FY +2 Year | FY +3 Year | FY +4 Year | FY +5 Year |
|---|---|---|---|---|---|---|
| **SAVINGS:** | $ | $ | $ | $ | $ | $ |
| **Regulated Community** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Local Government** | N/A | N/A | N/A | N/A | N/A | N/A |
| **State Government** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Total Savings** | | | | | | |
| **COSTS:** | | | | | | |
| **Regulated Community** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Local Government** | N/A | N/A | N/A | N/A | N/A | N/A |
| **State Government** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Total Costs** | | | | | | |
| **REVENUE LOSSES:** | | | | | | |
| **Regulated Community** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Local Government** | N/A | N/A | N/A | N/A | N/A | N/A |
| **State Government** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Total Revenue Losses** | | | | | | |

(17a) Provide the past three year expenditure history for programs affected by the regulation.

| Program | FY -08-09 | FY -09-10 | FY -10-11 | Current FY 11-12 |
|---|---|---|---|---|
| State Board of Nursing | $9,347,411.77 | $9,984,700.90 | $10,493,733.30 | $10,470000.00 (budgeted) |
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(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

**The public benefits by having LPNs able to perform to the full extent of their education, training and ability. The regulation also sets forth the parameters of IV therapy which also benefits the public in that the practice was unregulated before. Any costs would be minimal and only apply to those LPNs who do not have the training and want to engage in IV therapy. Therefore, the benefits to LPNs and the public outweigh any costs.**

(19) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

**The Board held many public work sessions in drafting this regulation. The sessions were attended by Board Counsel, Board staff, Board members, representatives from HAP, representatives from nursing schools and many other stakeholders.**

(20) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

**No alternative regulatory provisions were considered.**

(21) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

**There are no federal standards applicable here.**

(22) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

**This regulation will not put Pennsylvania at a competitive disadvantage with other states. All of the border states allow LPNs to perform IV therapy to some degree.**

(23) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

**The regulation will not affect the regulations of other state agencies. It will not affect other regulations of the promulgating agency other than the Nurse Board regulations that were amended in the promulgation of this regulation.**

(24) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

**There are no forms or reports required for implementation of the regulation.**

(25) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

**No groups with particular needs have been identified.**

(26) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: **The public comment period ended on May 31, 2010**

B. The date or dates on which public meetings or hearings will be held: **The Board held public work sessions during the drafting phase of the regulation. The Board discussed the public comments at its July 29, 2010 board meeting. The Board held public discussion and voted on the final-form regulation at its September 13-14, 2010, October 27-28, 2010 and October 20, 2011 meetings.**

C. The expected date of promulgation of the proposed regulation as a final-form regulation: **Summer 2012**

D. The expected effective date of the final-form regulation: **Upon publication**

E. The date by which compliance with the final-form regulation will be required: **Upon publication**

F. The date by which required permits, licenses or other approvals must be obtained: **N/A**

(27) Provide the schedule for continual review of the regulation.

**The Board reviews the effectiveness of its regulations on an ongoing basis.**

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# FACE SHEET
# FOR FILING DOCUMENTS
# WITH THE LEGISLATIVE REFERENCE BUREAU

**(Pursuant to Commonwealth Documents Law)**

DO NOT WRITE IN THIS SPACE

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Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Nursing
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5122

DATE OF ADOPTION: _____

BY: _____

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

Megan L. Consedine

MAY 12 2012
DATE OF APPROVAL

~~(Executive~~ Deputy General Counsel
Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

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# COMMONWEALTH OF PENNSYLVANIA
# DEPARTMENT OF STATE
# BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
# STATE BOARD OF NURSING
# 49 PA. CODE, CHAPTER 21
# IV Therapy Functions for Licensed Practical Nurses

The State Board of Nursing (Board) hereby amends §§ 21.141, 21.145 and 21.203 (relating to definitions; functions of the LPN; and specific curriculum requirements for practical nursing programs) and adds §§ 21.145a and 21.145b (relating to prohibited acts; and IV therapy curriculum requirements), to read as set forth in Annex A.

**Effective Date**

The amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin.*

**Statutory Authority**

The amendments are authorized by section 17.6 of the Practical Nurse Law (63 P.S. §667.6) (act), which authorizes the Board to establish rules and regulations for the practice of practical nursing.

**Background and Need for the Regulations**

The final-form regulations are necessary due to the increased utilization of peripherally inserted central catheters and other centrally inserted intravenous access devices in the patient population cared for in Pennsylvania hospitals and health systems. In addition, patients are being transferred to long-term care facilities with increasing frequency with complex IV access devices in place. Licensed practical nurses (LPNs) in Pennsylvania are being asked to provide services to these patients. These regulations will standardize LPN practice across the Commonwealth related to IV access devices and will provide mandates for the educational program that must be provided for LPNs working with IV access devices to ensure patient safety.

**Response to Comments**

The proposed rulemaking was published on May 1, 2010. The Board received comments from Jodi Yenchik, RNC-LRN, BSN, MJ, DL; Chester County Intermediate Unit (Chester County IU); Fresenius Medical Care North America (Fresenius); Kimberly Huff, RN, MSN; Cassandre Conti, LPN; and The Hospital & Healthsystem Association of Pennsylvania (HAP). The Board also received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC).

Dr. Yenchik, a nursing educator, wrote in support of the proposed regulations and did not offer any revisions. Ms. Huff asked whether the "patient-controlled administration system" in § 21.145(g)(11) referred to PCA pumps that would be administering narcotic analgesics such as Demerol. The Board intends the term to include PCA pumps that would be administering narcotic analgesics such as Demerol. Ms. Huff next asked how parenteral nutrition and fat emulsion solutions, referred to in § 21.145(g)(12), are different from total parenteral nutrition (TPN). They are not; TPN is another term for these types of solutions. Ms. Conti wrote to express her support of the proposed regulations in that they will improve the continuity of care for the patient.

Fresenius provides dialysis services for individuals undergoing dialysis due to end stage renal disease. Fresenius asked the Board to consider permitting LPNs in the dialysis setting to administer IV medications via push or bolus routes. The Board considered Fresenius' comment, but to be consistent with practice in other settings declined to add specific language at this time to allow LPNs to administer IV medications via push or bolus routes.

Chester County IU commented that two provisions in § 21.145 regarding authority to administer total parenteral nutrition are contradictory. The first provision is the current language that prohibits LPNs from administering total parenteral nutrition; and the second provision is the new language that permits LPNs to perform the administration, maintenance and discontinuance of parenteral nutrition and fat emulsion solutions. Chester County IU suggests amending the second provision to delete the word "administration." However, as indicated by the brackets, the first provision referenced by Chester County IU is being deleted from the regulations. This language is being replaced by the second provision, which allows an LPN who has met the education and training requirements set forth in the regulations to perform administration, maintenance and discontinuance of parenteral nutrition and fat emulsion solutions, also known as total parenteral nutrition. The Board intended to permit properly trained LPNs to administer total parenteral nutrition. For this reason, the Board has not made the suggested amendment. Chester County IU also commented that § 21.145(g)(10) should read "patency" instead of "potency." The Board agrees that it appears that a typographical error was made in the publication of the proposed rulemaking. Therefore, the Board has corrected the term in the final-form regulation.

Finally, Chester County IU commented that the term "focused assessment" was not used consistently throughout the proposed regulations. The Board has reviewed the entire regulation and changed terms it believed were inconsistent. HAP also commented and suggested that the Board reconsider the use of the term "focused assessment" and "assess" throughout the document. IRRC also questioned whether inclusion of this term expended the scope of practice of LPNs. HAP noted that many nurse leaders indicated that the Practical Nurse Act does not allow for assessment. The Board disagrees. While, the act does not specifically mention assessment, it also does not prohibit it. The Board believes that "focused assessment," as that term is defined in § 21.141, is an appropriate function of an LPN and vital in their role in the healthcare team. The definition is consistent with model regulations of the National Council of State Boards of Nursing (NCSBN). The Board is comfortable with the definition and the term's incorporation into the regulatory language.

HAP also commented that the Board should add the definition of "venous access device" because the term is used in § 21.145(g). While "venous access device" is not specifically used in § 21.145, the term "IV access device" is used. "IV access device" is defined in § 21.141. The Board notes that the term "venous access device" did appear in § 21.145b as proposed, but amendments to the final-form rulemaking have eliminated the use of that term. HAP further commented that the Board should give examples of "electronic communication" found in § 21.145(f)(4). The Board considered this comment but feels that examples are not needed in the regulation to improve clarity. HAP also commented that the Board should add a definition of "assistance readily available." The Board believes this term could have different meanings in

different practice settings. The Board prefers not to be too prescriptive in its regulations and would instead prefer to allow "assistance readily available" to be determined in accordance with generally accepted standards of practice in each practice setting. Additionally a search of the term "readily available" on Westlaw revealed that the term is used 142 times in state regulations and 1,051 times in federal regulations. Therefore the Board believes that healthcare settings are familiar with that "readily available" means.

HAP next commented that "maintenance" as used in § 21.145(g)(5) should be defined as there was some confusion among nurse leaders as to what they considered to be IV maintenance as opposed to site care. To address HAP's concerns the Board has included examples of maintenance functions in § 21.145(g)(5). HAP also asked that the Board define what is "therapeutic phlebotomy" as used in § 21.145a(14). The Board believes that the term has a generally accepted meaning in the medical community and does not need to be defined in the regulations.

HAP believes that an LPN should never be assigned to a patient whose condition is critical, fluctuating, unstable or unpredictable and recommended that § 21.145(f)(5)(i) be removed from the regulations. IRRC asked the Board to explain why this provision is needed and how it adequately protects the health, safety and welfare of the patient. The Board notes that in current practice LPNs are assigned to care for patients of this nature. The proposed regulation is written to require the LPN's supervisor to by physically present in the immediate vicinity of the LPN before an LPN may provide IV therapy to these patients. Therefore, the amendment provides an additional measure to protect the public health, safety and welfare in that it permits LPNs to continue to function in this role with a patient of this nature only when immediate assistance is available to intervene in the care of the patient if needed. As this is the current practice and the regulation adds the requirement that the LPN's supervisor be in the immediate vicinity, the public is better protected under these regulations than is the case now where this practice is unregulated. Therefore, the Board declines to remove this subsection.

HAP commented that nurse leaders were apprehensive about allowing LPNs to perform IV therapy related to central venous lines. However, HAP also noted that nurse leaders recognized the changing health care delivery system and the need to have LPNs care for patients with PICC lines in alternate care settings. The Board notes that LPNs are currently engaging in this practice, as well as teaching families to do some of these tasks. The Board appreciates HAP's concern with this area of LPN practice, but notes that in drafting these regulations it reviewed the regulations of other states as well as the model rules for LPNs and the Practical Nurse Scope of Practice White Paper published by the NCSBN and found support for allowing LPNs to perform IV therapy related to central venous lines.

HAP noted that the proposed rulemaking permits LPNs to observe and report subjective and objective signs of adverse reactions to any IV administration and to initiate appropriate interventions. HAP asked that the Board consider identifying in § 21.145(g)(2) what the appropriate interventions might be. As these interventions could be case, situation or setting specific the Board declines to add those to the regulation. HAP asked that § 21.145(g)(4) be revised and provided suggested language relating to performance of site care. The Board has adopted the suggested language (observation of the intravenous insertion site and performance of

insertion site care) and has added it to the final-form regulation. HAP also asked that the Board revise § 21.145(g)(10) to be specific about what solutions could be administered to maintain patency, and to limit it to "saline and heparin flushes." As practice moves faster than the Board is able to update regulations, the Board does not want to list specific solutions to be used. Additionally, HAP recommended that § 21.145(g)(13) be removed from the regulation because nurse leaders believed collecting blood specimens from an IV access device was not a good practice. The Board notes that in long term care and home care this is done regularly. The Board believes that collection of blood specimens from an IV access device is a legitimate use of these catheters, therefore the Board declines to make the change.

HAP commented that §21.145a(1) (relating to prohibited acts) should be clarified that LPNs may not accept orders for blood and blood components. The Board notes that orders are addressed in §21.145. Section 21.145(b)(1) allows an LPN to accept a written order for medication and therapeutic treatment. Section 21.145(b)(4) prohibits an LPN from accepting an oral order which is not within the scope of functions permitted by that section. If an LPN is prohibited from performing a function, it follows that an LPN may not accept either a written or oral order to perform that function. The Board believes that the prohibition on initiating administration of blood, blood components and plasma volume expanders is a strong enough prohibition without having to go further to say that the LPN cannot accept an order to do that prohibited function. HAP further recommended revising § 21.145a(15) to include deaccessing implantable devices. However, the Board believes that deaccessing these devices is less risky than accessing. Therefore, the Board declines to prohibit deaccessing devices.

HAP also commented regarding the IV therapy curriculum requirements and IRRC echoed these comments. HAP recommended including the number of hours and instructor qualifications. However, the Board generally does not specify hours and instructor qualifications for each type of course offered by LPN programs, and declines to do so for IV therapy courses. Instead the Board's regulations set out general faculty requirements in §§ 21.191 – 21.194 and curriculum requirements in §§ 21.201 – 21.204. The Board has revised the final-form regulation curriculum requirements to make them general, and therefore be more in line with the rest of the curriculum requirements, and moved them to § 21.203 where the curriculum requirements for LPN programs are located. The Board has also amended the final-form regulation to include the requirement that stand-alone IV therapy courses apply for approval from the Board and added a subsection to § 21.145b detailing what must be submitted for approval. While not promulgating instructor qualifications, the Board has clarified that the instructors must have knowledge and skill in the course content taught. This has been a requirement informally in effect as long as the Board has approved stand-alone IV therapy courses. The Board does not want to micromanage approved LPN education programs by telling them how many hours each area of the curriculum must encompass; therefore, the Board did not include that requirement in the final-form regulation. HAP also recommended a lab practicum in the curriculum requirements. For the reasons mentioned above, the Board declines to add the requirement for a lab practicum to the final-form regulation.

HAP and IRRC next asked whether the Board will approve LPN IV therapy courses or whether the Board will depend on other established groups to review and approve the courses. The Board will approve the stand-alone courses as described above. The onus is on the LPN to

ensure that they have the required knowledge, skill and ability to perform IV therapy. If the LPN decides that further education is needed, it is also incumbent upon the LPN to ensure that the IV therapy course is approved. The Board already approves practical nursing programs through the process set forth at §§21.161 et seq. therefore the curriculum content would be approved as part of that process for IV therapy courses that are part of a practical nursing program.

HAP also asked whether LPNs currently performing IV therapy would be required to complete an entire course in IV therapy or only selected portions of the curriculum. Section 21.145(g) says that "[a]n LPN who has met the education and training requirements of §21.145b (relating to IV therapy curriculum requirements) may perform the following IV therapy functions." In the final-form regulation §21.145b now refers to §21.203 for the education and training requirements. LPNs currently performing IV therapy would not necessarily be required to complete a course if they have education in the topics set forth in § 21.203. HAP also asked that the Board enact some continued competency requirements relating to IV therapy. This is not something the Board believes is necessary as the Board does not require continued competency for other specific aspects of practice for currently licensed LPNs, and to date the General Assembly has not required continuing education for LPNs.

HPLC commented that the regulation should consistently use the terms registered nurse, RN and licensed professional nurse. The Board has revised the final-form regulation to use only the term licensed professional nurse. HPLC next requested that the Board review § 21.203(d)(8) for consistency with the deletion of existing language in § 21.145(f). In the final-form regulation the Board has done so, including moving the curriculum requirements to § 21.203. HPLC also asked whether LPN programs should continue to provide, "Technical and clinical aspects of immunization, skin testing, the performance of venipuncture and the administration and withdrawal of intravenous fluid to the extent each function is authorized under this chapter." The revised regulations do not change this section of the regulation. They only expand on the IV therapy portion of it. For clarity, in the final-form regulation the Board moved the curriculum requirements to § 21.203(d)(8) and left the introductory sentence in § 21.203(d)(8) intact.

In addition to comments that echoed some of the concerns of the public commentators discussed above, IRRC questioned what effect the regulation would have on LPNs currently administering IV therapy that have not met the curriculum requirements of § 21.145b. Those LPNs who do not currently have the knowledge, skill and ability to perform IV therapy and those who have not completed IV therapy education as specified in the regulation will need further education if they wish to continue to provide IV therapy per the new regulations. IRRC also asked whether the Board considered providing a grandfathering provision to allow LPNs the necessary time to meet the curriculum requirements. The Board does not believe a grandfather clause is in the public interest because LPNs who do not possess the knowledge, skill and ability and who have not been trained should not be performing IV therapy under these regulations. IRRC also recommended that the Board define IV therapy. The Board has included a definition of the term in the final-form rulemaking.

IRRC next asked the Board to clarify who will provide the instruction and supervision required by § 21.145(a)(2) to an LPN implementing new or unfamiliar nursing practices or procedures. The instruction could be provided by any number of people working with the LPN,

including an RN working with the LPN or the LPN's supervisor. This is the current practice; the Board is merely codifying it. The Board declines to make a change to the regulation so as not to be too prescriptive regarding nursing practice.

IRRC suggested that the final-form regulation eliminate the phrases "readily available" and "immediate vicinity" found in § 21.145(f)(4) and (5) respectively because IRRC feels these terms are vague. The Board believes these terms to be clear. A Westlaw search revealed that the term "readily available" was used 142 times in state regulations and 1,051 times in federal regulations. Each practice setting would require a different standard as to what level of assistance is needed and how it may be made readily available. To change this language the board would have to list each different practice setting and attempt to define the level of assistance the LPN needs. This is an impossible task for the Board to undertake. The Board likewise believes that "immediate vicinity" is not a vague term. A Westlaw search revealed that the term "immediate vicinity" used 19 times in state regulations and 155 times in federal regulations. It is a term that has been defined as "near" or "close at hand." Again, "immediate vicinity" could change based on practice setting. To change this term, the Board would have to list each practice setting and be very prescriptive about how far away the LPN's supervisor could be at any time. The Board does not believe that the regulation could be amended in a way to make these sections more precise.

Finally, IRRC asked whether § 21.203 (related to specific curriculum requirements for practical nursing programs) should be amended to include a cross reference to § 21.145b (related to IV therapy curriculum requirements). The Board has amended both sections of the final-form regulation to move the IV therapy curriculum requirements to § 21.203.

## Fiscal Impact and Paperwork Requirements

The amendments will have no adverse fiscal impact on the Commonwealth or its political subdivisions, because the costs of the Board's activities are supported by fees charged to licensees and others who benefit from specific activities of the Board. The amendments will impose no additional paperwork requirements upon the Commonwealth or political subdivisions.

## Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

## Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on April 21, 2010, the Board submitted notice of this proposed rulemaking, published at 40 Pa.B. 2276 (May 1, 2010), to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on_____, 2012 the final-form rulemaking was approved by the HPLC. On _____, 2012, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, 2012, and approved the final-form rulemaking.

**Additional Information**

Additional information may be obtained by writing to Cynthia Miller, Board Administrator, State Board of Nursing, P.O. Box 2649, Harrisburg, PA 17105-2649.

**Findings**

The State Board of Nursing finds that:

(1) Public notice of intention to adopt a regulation at 49 Pa. Code, Chapter 21, was given under sections 201 and 202 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201-1202) and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1-7.2.

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to the final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1201).

(4) These amendments to the regulations of the State Board of Nursing are necessary and appropriate for the regulation of the practice of professional nurses in the Commonwealth.

**Order**

The Board therefore ORDERS that:

(A) The regulations of the State Board of Nursing, 49 Pa. Code, Chapter 21, are amended to read as set forth in Annex A.

(B) The Board shall submit a copy of Annex A to the Office of the Attorney General and the Office of General Counsel for approval as required by law.

(C) The Board shall certify this Order and Annex and shall deposit them with the Legislative Reference Bureau as required by law.

(D) The regulations shall take effect immediately upon publication in the Pennsylvania Bulletin.

Joseph Napolitano, Ph.D. MPH, RN, CRNP,
Chairman
State Board of Nursing

**ANNEX A**

**PENNSYLVANIA ADMINISTRATIVE CODE**

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**

**PART I. DEPARTMENT OF STATE**

**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

**CHAPTER 21. STATE BOARD OF NURSING**

**Subchapter B. PRACTICAL NURSES**

**GENERAL PROVISIONS**

**§ 21.141. Definitions.**

The following words and terms, when used in this subchapter have the following meanings, unless the context clearly indicates otherwise:

* * * * *

*Bolus* – A concentrated medication or solution given rapidly over a short period of time.

*Central venous catheter* – An intravenous (IV) catheter, the tip of which terminates ~~in the superior vena cava~~ BEYOND THE PERIPHERAL VASCULATURE and may be either tunneled, implanted, or percutaneously inserted.

* * * * *

*Focused assessment* – Appraisal of an individual's current status and situation, which contributes to comprehensive assessment by the ~~registered~~ LICENSED PROFESSIONAL nurse and supports ongoing data collection.

* * * * *

*IV access device* – A centrally or peripherally inserted catheter used for the purpose of intravenous infusion therapy, including peripheral short catheters, peripheral midline catheters, peripherally inserted central catheters and central catheters, INCLUDING TUNNELED, NON-TUNNELED CATHETERS AND IMPLANTED PORTS.

IV THERAPY – THE ADMINISTRATION OF FLUIDS, ELECTROLYTES, NUTRIENTS, OR MEDICATIONS BY THE VENOUS ROUTE.

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*PICC – Peripherally inserted central catheter* – An IV catheter, the tip of which terminates in the superior vena cava and is confirmed by chest x-ray.

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*Peripheral midline catheter* – A peripherally inserted catheter, the tip of which terminates no further than the axilla and is between 3 inches and 8 inches (7.5 cm and 20 cm) in length.

*Peripheral short catheter* – A venous access device less than 3 inches (7.5 cm) in length.

* * * * *

*Titration of IV medications* – A process by which medication is administered and dosages are adjusted through a continuous medication-containing intravenous infusion (such as vasoactive drugs, anticoagulants, psychotropic drugs, neuromuscular drugs, hormones, and the like) in order to effect a desired state based upon patient assessment data and prescribed parameters.

**§ 21.145. Functions of the LPN.**

(a) The LPN is prepared to function as a member of the health-care team by exercising sound nursing judgment based on preparation, knowledge, [skills, understandings and past experiences in nursing situations] experience in nursing and competency. The LPN participates in the planning, implementation and evaluation of nursing care using focused assessment in settings where nursing takes place.

(1) An LPN shall communicate with ~~an RN~~ A LICENSED PROFESSIONAL NURSE and the patient's health care team members to seek guidance when:

(i) The patient's care needs exceed the licensed practical nursing scope of practice.

(ii) The patient's care needs surpass the LPN's knowledge, skill or ability.

(iii) 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.

(2) An LPN shall obtain instruction and supervision if implementing new or unfamiliar nursing practices or procedures.

(3) An LPN shall follow the written, established policies and procedures of the facility that are consistent with the act.

* * * * *

(f) [The LPN may perform venipuncture and administer and withdraw intravenous fluids only if the following conditions are met:

(1) The LPN has received and satisfactorily completed a Board approved educational program which requires study and supervised clinical practice intended to provide training necessary for the performance of venipuncture and the administration and withdrawal of intravenous fluids as authorized by this section.

(2) A specific written order has been issued by a licensed physician for an individual patient under the care of a licensed physician.

(3) The LPN complies with written policies and procedures which are established by a committee of nurses, physicians, pharmacists and the administration of the agency or institution employing or having jurisdiction over the LPN and which set forth standards, requirements and guidelines for the performance of venipuncture by the LPN and for the administration and withdrawal of intravenous fluids by the LPN. A current copy of the policies and procedures shall be provided to the LPN at least once every 12 months. The policies and procedures shall include standards, requirements and guidelines which:

(i) List, identify and describe the intravenous fluids which may be administered by the LPN. The LPN is not authorized to administer the following intravenous fluids:

(A) Antineoplastic agents.

(B) Blood and blood products.

(C) Total parenteral nutrition.

(D) Titrated medications and intravenous push medications other than heparin flush.

(ii) List, identify and describe the circumstances under which venipuncture may be performed, including technical and clinical indications.

(iii) List, identify, describe and explain principles, including technical and clinical indications, necessary for the identification and treatment of possible adverse reactions.

(iv) Provide for and require inservice instruction and supervised practice to insure competent performance of venipuncture and competent administration and withdrawal of intravenous fluids.

(4) An accurate record is made concerning:

(i) The time of puncture or injection or withdrawal of the intravenous fluid.

(ii) The type of intravenous fluid injected.

(iii) The amount of intravenous fluid injected.

(iv) The site of the puncture of injection.

(v) Reactions to the puncture or the intravenous fluid injected.]

An LPN may perform only such IV therapy functions for which the LPN possesses the knowledge, skill and ability to perform in a safe manner, except as limited by § 21.145a (relating to prohibited acts), and only under supervision as required by paragraph (1).

(1) An LPN may initiate and maintain IV therapy only under the direction and supervision of a licensed professional nurse or health care provider authorized to issue orders for medical therapeutic or corrective measures (such as a CRNP, physician, physician assistant, podiatrist or dentist).

(2) Prior to the initiation of IV therapy, an LPN shall:

(i) Verify the order and identity of the patient.

(ii) ~~Assess the patient for~~ IDENTIFY allergies, fluid and medication compatibilities.

(iii) ~~Assess~~ MONITOR the patient's circulatory system and infusion site.

(iv) ~~Assess~~ INSPECT all equipment.

(v) Instruct the patient regarding the risk and complication of therapy.

(3) Maintenance of IV therapy by an LPN must include ongoing observation and focused assessment of the patient, monitoring the IV site and maintaining the equipment.

(4) For a patient whose condition is determined by the LPN's supervisor to be stable and predictable, and rapid change is not anticipated, the supervisor

may supervise the LPN's provision of IV therapy by physical presence or electronic communication. If supervision is provided by electronic communication, the LPN shall have access to assistance readily available.

(5) In the following cases, an LPN may provide IV therapy only when the LPN's supervisor is physically present in the immediate vicinity of the LPN and immediately available to intervene in the care of the patient:

(i) When a patient's condition is critical, fluctuating, unstable or unpredictable.

(ii) When a patient has developed signs and symptoms of an IV catheter-related infection, venous thrombosis or central line catheter occlusion.

(iii) When a patient is receiving hemodialysis.

(g) [The Board will issue annually to the LPN definitive information describing the nature, scope and extent of authorized functions and practice concerning immunization, skin testing, venipuncture and the administration and withdrawal of intravenous fluids.]

An LPN who has met the education and training requirements of § 21.145b (relating to IV therapy curriculum requirements) may perform the following IV therapy functions, except as limited by § 21.145a and only under supervision as required by subsection (f):

(1) Adjustment of the flow rate on IV infusions.

(2) Observation and reporting of subjective and objective signs of adverse reactions to any IV administration and initiation of appropriate interventions.

(3) Administration of IV fluids and medications.

(4) ~~Performance of site care.~~ OBSERVATION OF THE IV INSERTION SITE AND PERFORMANCE OF INSERTION SITE CARE.

(5) Performance of maintenance. MAINTENANCE SHALL INCLUDE DRESSING CHANGES, IV TUBING CHANGES, AND SALINE OR HEPARIN FLUSHES.

(6) Discontinuance of a medication or fluid infusion, including infusion devices.

(7) Conversion of a continuous infusion to an intermittent infusion.

(8) Insertion or removal of a peripheral short catheter.

(9) Maintenance, monitoring and discontinuance of blood, blood components and plasma volume expanders.

(10) Administration of solutions to maintain ~~potency~~ PATENCY of an IV access device via direct push or bolus route.

(11) Maintenance and discontinuance of IV medications and fluids given via a patient-controlled administration system.

(12) Administration, maintenance and discontinuance of parenteral nutrition and fat emulsion solutions.

(13) Collection of blood specimens from an IV access device.

**§ 21.145a. Prohibited acts.**

An LPN may not perform the following IV therapy functions:

(1) Initiate administration of blood, blood components and plasma volume expanders.

(2) Administer tissue plasminogen activators, immunoglobulins, antineoplastic agents or investigational drugs.

(3) Access a central venous route access device used for hemodynamic monitoring.

(4) Administer medications or fluids via arterial lines.

(5) Administer medications via push or bolus route.

(6) Administer fibrinolytic or thrombolytic agents to declot any IV access device.

(7) Administer medications requiring titration.

(8) Insert or remove any IV access device, except a peripheral short catheter.

(9) Access or program an implanted IV infusion pump.

(10) Administer IV medications for the purpose of procedural sedation or anesthesia.

(11) Administer fluids or medications via an epidural, intrathecal, intraosseous or umbilical route, or via a ventricular reservoir.

(12) Administer medications or fluids via an arteriovenous fistula or graft, except for dialysis.

(13) Perform repair of a central venous route access device or PICC.

(14) Perform therapeutic phlebotomy.

(15) Direct access of implantable devices.

**§ 21.145b. IV therapy curriculum requirements.**

(A) An IV therapy course provided as part of the LPN education curriculum as set forth in § 21.203 (relating to specific curriculum requirements for practical nursing programs) or as a stand-alone course offered by a ~~licensed health care facility~~ PROVIDER shall include instruction ~~in the following topics:~~ IN THE TOPICS SET FORTH IN §21.203(D)(8). INSTRUCTORS OF A STAND-ALONE COURSE SHALL HAVE KNOWLEDGE AND SKILL IN THE ASPECT OF THE COURSE CONTENT TAUGHT.

~~(1) IV Infusion Therapy, as follows:~~

~~(i) Definition of IV therapy.~~

~~(ii) Indications:~~

~~(A) Fluid volume maintenance.~~

~~(B) Fluid volume replacement.~~

~~(C) Medication administration.~~

~~(D) Blood and blood product maintence, monitoring and discontinuation.~~

~~(E) Nutritional support.~~

~~(iii) Types of vascular access delivery devices:~~

~~(A) Venous access devices.~~

~~(B) Central venous access devices.~~

~~(C) Peripherally inserted central venous access devices.~~

~~(iv) Age-related considerations and IV therapy (generally and within each major area as appropriate):~~

~~(A) Pediatric patients.~~

~~(B) Adult patients.~~

~~(C) Elderly patients.~~

~~(2) Legal implications for IV nursing practice:~~

~~(i) *Pennsylvania Code* Title 49, Chapter 21, Subchapter B. Practical Nurses.~~

~~(ii) Institutional policy and procedure.~~

~~(iii) Standards of practice.~~

~~(iv) Accountability in infusion therapy.~~

~~(v) Malpractice liability.~~

~~(vi) Documentation.~~

~~(vii) Quality assurance.~~

~~(viii) Continuing education.~~

~~(ix) Patient rights.~~

~~(3) Related anatomy and physiology (including age-related differences).~~

~~(4) Fundamentals of fluid balance and electrolyte balance (including age-related differences).~~

~~(5) Equipment and supplies used in the preparation and administration of IV therapy:~~

~~(i) Administration sets:~~

~~(A) Primary.~~

~~(B) Secondary or piggyback, saline lock, Y-type administration with controlled volume, filters.~~

~~(ii) Needleless systems.~~

~~(iii) Venous access devices.~~

~~(iv) Infusion site preparation and site dressing materials.~~

~~(v) Infusion regulation systems (pumps and controllers).~~

~~(vi) Labels.~~

~~(vii) Hanging devices.~~

~~(6) Parenteral solutions and indications for use (isotonic, hypotonic, hypertonic).~~

~~(7) Infection control and safety issues:~~

~~(i) Transmission.~~

~~(ii) Types of infections:~~

~~(A) Local.~~

~~(B) Systemic.~~

~~(iii) Prevention measures.~~

~~(iv) Standard precautions.~~

~~(8) Insertion of peripheral short catheters (theory and lab):~~

~~(i) Equipment.~~

~~(ii) Site selection.~~

~~(iii) Site preparation.~~

~~(iv) Inserting the IV access device.~~

~~(v) Dressing the site.~~

~~(vi) Documentation.~~

~~(9) Administration, maintenance and monitoring of peripheral IV therapy (theory and lab):~~

~~(i) Focused assessment pertaining to IV therapy.~~

~~(ii) Calculating IV rate.~~

~~(iii) Terminology.~~

~~(iv) Drug compatibility.~~

~~(v) Drug information.~~

~~(vi) Methods/technique of administering IV medications/fluids.~~

~~(vii) Continuous and intermittent monitoring of IV medications/fluids.~~

~~(viii) Local complications and nursing interventions:~~

~~(A) Phlebitis/thrombosis.~~

~~(B) Infiltration/extravasation.~~

~~(C) Catheter displacement.~~

~~(D) Occlusion.~~

~~(E) Hematoma.~~

~~(F) Cellulitis.~~

~~(G) Local infection.~~

~~(ix) Systemic complications:~~

~~(A) Sepsis.~~

~~(B) Medication and fluid interactions.~~

~~(C) Allergic reactions.~~

~~(D) Embolism.~~

~~(x) Documentation.~~

~~(xi) Discontinuing a peripheral IV.~~

~~(10) Centrally and peripherally placed vascular access devices:~~

~~(i) Indications for centrally placed devices.~~

~~(ii) Disadvantages and advantages.~~

~~(iii) Placement of devices:~~

~~(A) Review anatomy.~~

~~(B) Usual sites.~~

~~(C) Types of devices:~~

~~(I) Tunneled.~~

~~(II) Nontunneled.~~

~~(III) Implanted ports.~~

~~(IV) PICC.~~

~~(iv) Insertion-related complications:~~

~~(A) Pneumothorax.~~

~~(B) Air embolism.~~

~~(C) Catheter malposition.~~

~~(D) Mediastinal injury.~~

~~(E) Hemothorax.~~

~~(F) Chylothorax.~~

~~(G) Hydrothorax.~~

~~(H) Brachial plexus injury.~~

~~(I) Arterial laceration.~~

~~(J) Extravascular malposition.~~

~~(K) Intravascular malposition.~~

~~(L) Pericardial tamponade.~~

~~(v) Long term complications:~~

~~(A) Dislodgement.~~

~~(B) Air embolism.~~

~~(C) Local infection.~~

~~(D) Sepsis.~~

~~(E) Catheter migration.~~

~~(F) Catheter occlusion.~~

~~(G) Vessel thrombosis.~~

~~(H) Damaged catheter.~~

~~(I) Superior Vena Cava Syndrome.~~

~~(J) Skin erosion.~~

~~(vi) Maintaining central venous infusions (differentiate for types of access devices):~~

~~(A) Checking placement.~~

~~(B) Changing dressings.~~

~~(C) Changing IV tubing & solution.~~

~~(D) Changing catheter cap.~~

~~(E) Flushing.~~

~~(F) Administering primary or secondary infusion.~~

~~(G) Obtaining a blood sample.~~

~~(H) Determining intake and output.~~

~~(I) Documenting.~~

~~(11) Special considerations:~~

~~(i) Setting:~~

~~(A) Acute care.~~

~~(B) Home care.~~

~~(C) Long term care.~~

~~(D) Ambulatory care.~~

~~(E) Hospice care.~~

~~(ii) Patient education.~~

~~(iii) Ethical/cultural issues.~~

~~(iv) Other geographical practice setting differences.~~

(B) PROVIDERS OF STAND-ALONE COURSES SHALL APPLY FOR APPROVAL FROM THE BOARD BEFORE OFFERING AN IV THERAPY COURSE. THE REQUEST FOR APPROVAL MUST INCLUDE THE FOLLOWING:

(1) A COURSE OUTLINE THAT INCLUDES ALL COMPONENTS OF THE IV THERAPY COURSE REQUIRED BY § 21.203(D)(8).

(2) A DESCRIPTION OF THE METHODS OF INSTRUCTION AND THE CLINICAL LEARNING EXPERIENCES PROVIDED.

(3) A DESCRIPTION OF SPECIFIC METHODOLOGIES AND TOOLS THAT EVALUATE THE LEARNER'S ACHIEVEMENT OF THE OBJECTIVES.

(4) A LIST OF FACULTY MEMBERSHIP AND VERIFICATION THAT THE INSTRUCTORS HAVE KNOWLEDGE AND SKILL IN THE ASPECT OF THE CONTENT TAUGHT.

**§ 21.203. Specific curriculum requirements for practical nursing programs.**

* * * * *

(d) The curriculum shall provide instruction in the following areas:

* * * * *

(8) Technical and clinical aspects of immunization, skin testing, the performance of venipuncture and the administration and withdrawal of intravenous fluids to the extent each function is an authorized function of an LPN under this chapter. ~~This curriculum shall be incorporated into the Practical Nursing Program by August 5, 1990.~~ AN IV THERAPY COURSE MUST INCLUDE INSTRUCTION IN THE FOLLOWING TOPICS:

(1) DEFINITION OF IV THERAPY AND INDICATIONS.

(2) TYPES OF VASCULAR ACCESS DELIVERY DEVICES.

(3) AGE-RELATED CONSIDERATIONS.

(4) LEGAL IMPLICATIONS FOR IV THERAPY.

(5) ANATOMY AND PHYSIOLOGY.

(6) FLUID AND ELECTROLYTE BALANCE.

(7) INFUSION EQUIPMENT USED IN IV THERAPY.

(8) PARENTAL SOLUTIONS AND INDICATIONS.

(9) INFECTION CONTROL AND SAFETY.

(10) INSERTION OF PERIPHERAL SHORT CATHETERS.

(11) ADMINISTRATION, MAINTENANCE AND MONITORING OF PERIPHERAL IV THERAPY.

(12) COMPLICATIONS AND NURSING INTERVENTIONS.

(13) CENTRAL AND PERIPHERAL VASCULAR DEVICES.

(14) ADMINISTRATION, MAINTENANCE AND MONITORING OF CENTRAL AND PERIPHERAL IV THERAPY.

(15) DOCUMENTATION.

(16) PATIENT EDUCATION.

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**(3) Neither the DSP nor its affiliated interest has withheld from the market any generation supply in a manner that violates Federal law.**

* * * * *

**(g) If a customer chooses an alternative supplier and subsequently desires to return to the local distribution company for generation service, the local distribution company shall treat that customer exactly as it would any new applicant for energy service.**

**(h) A DSP may, in its sole discretion, offer large customers with a peak demand of 15 megawatts or greater at one meter location in its service territory any negotiated rate for service at all of the customers' locations within the service territory for any duration agreed upon by the DSP and the customer.**

**(1) Contract rates shall be subject to Commission review to ensure all costs are borne by the parties to the contract and no one else.**

**(2) If no costs related to the rates are borne by other customers, the Commission will approve the contract within 90 days of its filing at the Commission. If the Commission does not approve the contract within the 90-day period, it shall be deemed approved.**

**(i) The DSP shall offer residential and small business customers a generation supply service rate that shall change no more frequently than on a quarterly basis. Default service rates shall be reviewed by the Commission to ensure that the costs of providing service to each customer class are not subsidized by any other class.**

[Pa.B. Doc. No. 10-772. Filed for public inspection April 30, 2010, 9:00 a.m.]

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# STATE BOARD OF NURSING

## [ 49 PA. CODE CH. 21 ]

## IV Therapy Functions for Licensed Practical Nurses

The State Board of Nursing (Board) proposes to amend §§ 21.141 and 21.145 (relating to definitions; and functions of the LPN) and to add §§ 21.145a and 21.145b (relating to prohibited acts; and IV therapy curriculum requirements), to read as set forth in Annex A. This proposal is intended to establish the requirements for licensed practical nurses to perform nursing functions involving intravenous access devices.

*Effective Date*

The proposed amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

*Statutory Authority*

The proposed amendments are authorized under section 17.6 of the Practical Nurse Law (63 P. S. § 667.6) (act), which authorizes the Board to establish rules and regulations for the practice of practical nursing.

*Background and Need for the Amendments*

The proposed amendments are necessary due to the increased utilization of peripherally inserted central catheters and other centrally inserted intravenous access devices in the patient population cared for in this Commonwealth's hospitals and health systems. In addition, patients are being transferred to long-term care facilities with increasing frequency with complex IV access devices in place. Licensed practical nurses (LPNs) in this Commonwealth are being asked to provide services to these patients. This proposal will standardize LPN practice across this Commonwealth related to IV access devices and will provide mandates for the educational program that must be provided for LPNs working with IV access devices to ensure patient safety.

*Description of Proposed Amendments*

*§ 21.141. Definitions.*

The Board proposes to add definitions of key terms used in its rulemaking regarding IV therapy. Specifically, the Board found it necessary to define the following terms: "bolus," "central venous catheter," "focused assessment," "IV access device," "peripheral short catheter," "peripheral midline catheter," "peripherally inserted central catheter (PICC)," and "titration of IV medications." The definitions used are consistent with those that are generally accepted by the health care community.

*§ 21.145. Functions of the LPN.*

The Board proposes to amend § 21.145. The Board proposes to update the language in § 21.145(a). In addition, the Board proposes to provide specific mandates which will require an LPN to consult with an RN and members of the patient's health care team authorized to issue orders for medical therapeutic or corrective measures (a CRNP, physician, physician assistant, podiatrist or dentist) and seek guidance if the patient's care needs exceed the LPN's scope of practice, surpass the LPN's knowledge, skill or ability, or if the patient's condition becomes unstable or immediate assistance is needed. These provisions should help to ensure that LPNs do not exceed their authorized scope of practice and an LPN attempting to provide care beyond the LPN's ability does not compromise patient care.

The Board proposes to require that an LPN obtain instruction and supervision if the LPN is implementing nursing practices or procedures that are new or unfamiliar to the LPN. This provision is intended to ensure that the LPN can competently perform all practices and procedures the LPN is expected to perform.

The Board proposes to require an LPN to follow the written, established policies and procedures of the employing facility that are consistent with the act. The prior absence of such a provision has hampered the Board's ability to protect the public when an LPN has failed to conform his conduct to facility policy, creating a risk that negligence and patient harm will occur, but where no other statutory or regulatory provision has been violated.

Finally, the Board proposes to strike the current language in § 21.145(f) and (g) regarding venipuncture and IV fluids which is greatly out of date, is not consistent with the current education and on-the-job training of LPNs, and is not consistent with the current utilization of LPNs in this Commonwealth's health care facilities. The Board proposes to replace this language with new § 21.145(f) and (g).

The proposed new § 21.145(f) would provide that an LPN may only perform IV therapy acts for which the LPN possesses the knowledge, skill and ability to safely perform and shall perform these acts under direction and

supervision as set forth therein. Paragraph (1) generally provides that an RN, CRNP, physician, physician assistant, podiatrist or dentist shall supervise an LPN performing IV therapy acts. Paragraph (2) allows an LPN to be under either physical presence supervision or electronic communication when the patient's condition is stable and predictable. Paragraph (3) provides for the level of supervision required if the patient's condition is not stable and predictable; in these cases, physical presence of the supervisor is required.

Section 21.145(g) provides that only LPNs who have met the education and training requirements in § 21.145b may perform IV therapy acts. The paragraphs that follow set forth the specific IV therapy acts that LPNs may perform. Notably, the proposed rulemaking does not expand LPNs scope of practice related to the insertion or removal of IV access devices, as under current regulations, § 21.145(g)(8) authorizes an LPN to insert or remove only a peripheral short catheter. The remaining enumerated functions in subsection (g) apply to all IV access devices; however, an LPN may not insert or remove any other type of IV access device.

*§ 21.145a. Prohibited acts.*

The Board proposes to add a new § 21.145a, which will set forth the IV therapy acts that an LPN is prohibited from performing.

*§ 21.145b. IV therapy curriculum requirements.*

The Board proposes to add a new § 21.145b, which will set forth the curriculum requirements that an LPN will have to complete to perform IV therapy acts as set forth in § 21.145(g). The educational component may be included in the LPN curriculum in the approved schools of practical nursing in this Commonwealth or may be stand-alone courses offered through the approved schools of practical nursing or through health care facilities.

*Compliance with Executive Order 1996-1*

The Board provided an exposure draft of its proposal to stakeholders in early 2007. The Hospital and Healthsystem Association of Pennsylvania, the Pennsylvania Homecare Association and several individual nurses provided comments and suggestions to the Board that were incorporated into the proposed rulemaking. In addition, comments and suggestions were provided by the Independent Regulatory Review Commission (IRRC).

*Fiscal Impact and Paperwork Requirements*

The proposed amendments will not have an adverse fiscal impact on the Commonwealth or its political subdivisions as the Board is self-supporting. The proposed amendments will not impose any additional paperwork requirements upon the Commonwealth or its political subdivisions. To the extent that private sector providers of practical nursing education will be required to amend their curricula, there may be costs associated with the proposal. However, it is the Board's understanding, after meeting with educational program officials that the programs are willing to amend their curricula to meet the current demands of practice on LPNs. In addition, based on its meetings with representatives of HAP, the majority of hospitals and health care systems in this Commonwealth currently have IV therapy training programs for LPNs.

*Sunset Date*

The Board continuously monitors the cost-effectiveness of its regulations. Therefore, no sunset date has been assigned.

*Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 21, 2010, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to IRRC and to the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

*Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Ann Steffanic, Board Administrator, State Board of Nursing, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

ANN O'SULLIVAN,
*Chair*

**Fiscal Note:** 16A-5122. No fiscal impact; (8) recommends adoption.

**Annex A**

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**

**PART I. DEPARTMENT OF STATE**

**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

**CHAPTER 21. STATE BOARD OF NURSING**

**Subchapter B. PRACTICAL NURSES**

**GENERAL PROVISIONS**

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* * * * *

***Focused assessment*—Appraisal of an individual's current status and situation, which contributes to comprehensive assessment by the registered nurse and supports ongoing data collection.**

* * * * *

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* * * * *

*PICC—Peripherally inserted central catheter*—An IV catheter, the tip of which terminates in the superior vena cava and is confirmed by chest x-ray.

* * * * *

*Peripheral midline catheter*—A peripherally inserted catheter, the tip of which terminates no further than the axilla and is between 3 inches and 8 inches (7.5 cm and 20 cm) in length.

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* * * * *

*Titration of IV medications*—A process by which medication is administered and dosages are adjusted through a continuous medication-containing intravenous infusion (such as vasoactive drugs, anticoagulants, psychotropic drugs, neuromuscular drugs, hormones, and the like) in order to effect a desired state based upon patient assessment data and prescribed parameters.

§ 21.145. Functions of the LPN.

(a) The LPN is prepared to function as a member of the health-care team by exercising sound nursing judgment based on preparation, knowledge, [ skills, understandings and past experiences in nursing situations ] experience in nursing and competency. The LPN participates in the planning, implementation and evaluation of nursing care using focused assessment in settings where nursing takes place.

(1) An LPN shall communicate with an RN and the patient's health care team members to seek guidance when:

(i) The patient's care needs exceed the licensed practical nursing scope of practice.

(ii) The patient's care needs surpass the LPN's knowledge, skill or ability.

(iii) 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.

(2) An LPN shall obtain instruction and supervision if implementing new or unfamiliar nursing practices or procedures.

(3) An LPN shall follow the written, established policies and procedures of the facility that are consistent with the act.

* * * * *

(f) [ The LPN may perform venipuncture and administer and withdraw intravenous fluids only if the following conditions are met:

(1) The LPN has received and satisfactorily completed a Board approved educational program which requires study and supervised clinical practice intended to provide training necessary for the performance of venipuncture and the administration and withdrawal of intravenous fluids as authorized by this section.

(2) A specific written order has been issued by a licensed physician for an individual patient under the care of a licensed physician.

(3) The LPN complies with written policies and procedures which are established by a committee of nurses, physicians, pharmacists and the administration of the agency or institution employing or having jurisdiction over the LPN and which set forth standards, requirements and guidelines for the performance of venipuncture by the LPN and for the administration and withdrawal of intravenous fluids by the LPN. A current copy of the policies and procedures shall be provided to the LPN at least once every 12 months. The policies and procedures shall include standards, requirements and guidelines which:

(i) List, identify and describe the intravenous fluids which may be administered by the LPN. The LPN is not authorized to administer the following intravenous fluids:

(A) Antineoplastic agents.

(B) Blood and blood products.

(C) Total parenteral nutrition.

(D) Titrated medications and intravenous push medications other than heparin flush.

(ii) List, identify and describe the circumstances under which venipuncture may be performed, including technical and clinical indications.

(iii) List, identify, describe and explain principles, including technical and clinical indications, necessary for the identification and treatment of possible adverse reactions.

(iv) Provide for and require inservice instruction and supervised practice to insure competent performance of venipuncture and competent administration and withdrawal of intravenous fluids.

(4) An accurate record is made concerning:

(i) The time of puncture or injection or withdrawal of the intravenous fluid.

(ii) The type of intravenous fluid injected.

(iii) The amount of intravenous fluid injected.

(iv) The site of the puncture of injection.

(v) Reactions to the puncture or the intravenous fluid injected. ]

An LPN may perform only the IV therapy functions for which the LPN possesses the knowledge, skill and ability to perform in a safe manner, except as limited under § 21.145a (relating to prohibited acts), and only under supervision as required under paragraph (l).

(1) An LPN may initiate and maintain IV therapy only under the direction and supervision of a licensed professional nurse or health care provider authorized to issue orders for medical therapeutic or corrective measures (such as a CRNP, physician, physician assistant, podiatrist or dentist).

(2) Prior to the initiation of IV therapy, an LPN shall:

(i) Verify the order and identity of the patient.

(ii) Assess the patient for allergies, fluid and medication compatibilities.

(iii) Assess the patient's circulatory system and infusion site.

(iv) Assess all equipment.

(v) Instruct the patient regarding the risk and complication of therapy.

**(3) Maintenance of IV therapy by an LPN must include ongoing observation and focused assessment of the patient, monitoring the IV site and maintaining the equipment.**

**(4) For a patient whose condition is determined by the LPN's supervisor to be stable and predictable, and rapid change is not anticipated, the supervisor may supervise the LPN's provision of IV therapy by physical presence or electronic communication. If supervision is provided by electronic communication, the LPN shall have access to assistance readily available.**

**(5) In the following cases, an LPN may provide IV therapy only when the LPN's supervisor is physically present in the immediate vicinity of the LPN and immediately available to intervene in the care of the patient:**

**(i) When a patient's condition is critical, fluctuating, unstable or unpredictable.**

**(ii) When a patient has developed signs and symptoms of an IV catheter-related infection, venous thrombosis or central line catheter occlusion.**

**(iii) When a patient is receiving hemodialysis.**

(g) **[ The Board will issue annually to the LPN definitive information describing the nature, scope and extent of authorized functions and practice concerning immunization, skin testing, venipuncture and the administration and withdrawal of intravenous fluids. ]**

**An LPN who has met the education and training requirements of § 21.145b (relating to IV therapy curriculum requirements) may perform the following IV therapy functions, except as limited under § 21.145a and only under supervision as required under subsection (f):**

**(1) Adjustment of the flow rate on IV infusions.**

**(2) Observation and reporting of subjective and objective signs of adverse reactions to any IV administration and initiation of appropriate interventions.**

**(3) Administration of IV fluids and medications.**

**(4) Performance of site care.**

**(5) Performance of maintenance.**

**(6) Discontinuance of a medication or fluid infusion, including infusion devices.**

**(7) Conversion of a continuous infusion to an intermittent infusion.**

**(8) Insertion or removal of a peripheral short catheter.**

**(9) Maintenance, monitoring and discontinuance of blood, blood components and plasma volume expanders.**

**(10) Administration of solutions to maintain potency of an IV access device via direct push or bolus route.**

**(11) Maintenance and discontinuance of IV medications and fluids given via a patient-controlled administration system.**

**(12) Administration, maintenance and discontinuance of parenteral nutrition and fat emulsion solutions.**

**(13) Collection of blood specimens from an IV access device.**

(*Editor's Note*: The following sections are new and the text has been printed in regular print to enhance readability.)

**§ 21.145a. Prohibited acts.**

An LPN may not perform the following IV therapy functions:

(1) Initiate administration of blood, blood components and plasma volume expanders.

(2) Administer tissue plasminogen activators, immunoglobulins, antineoplastic agents or investigational drugs.

(3) Access a central venous route access device used for hemodynamic monitoring.

(4) Administer medications or fluids via arterial lines.

(5) Administer medications via push or bolus route.

(6) Administer fibrinolytic or thrombolytic agents to declot any IV access device.

(7) Administer medications requiring titration.

(8) Insert or remove any IV access device, except a peripheral short catheter.

(9) Access or program an implanted IV infusion pump.

(10) Administer IV medications for the purpose of procedural sedation or anesthesia.

(11) Administer fluids or medications via an epidural, intrathecal, intraosseous or umbilical route, or via a ventricular reservoir.

(12) Administer medications or fluids via an arteriovenous fistula or graft, except for dialysis.

(13) Perform repair of a central venous route access device or PICC.

(14) Perform therapeutic phlebotomy.

(15) Direct access of implantable devices.

**§ 21.145b. IV therapy curriculum requirements.**

An IV therapy course provided as part of the LPN education curriculum as set forth in § 21.203 (relating to specific curriculum requirements for practical nursing programs) or as a stand-alone course offered by a licensed health care facility shall include instruction in the following topics:

(1) IV Infusion Therapy, as follows:

(i) Definition of IV therapy.

(ii) Indications:

(A) Fluid volume maintenance.

(B) Fluid volume replacement.

(C) Medication administration.

(D) Blood and blood product maintenance, monitoring and discontinuation.

(E) Nutritional support.

(iii) Types of vascular access delivery devices:

(A) Venous access devices.

(B) Central venous access devices.

(C) Peripherally inserted central venous access devices.

(iv) Age-related considerations and IV therapy (generally and within each major area as appropriate):

(A) Pediatric patients.

(B) Adult patients.

(C) Elderly patients.

(2) Legal implications for IV nursing practice:

(i) *Pennsylvania Code*—Title 49, Chapter 21, Subchapter B. Practical Nurses.

(ii) Institutional policy and procedure.

(iii) Standards of practice.

(iv) Accountability in infusion therapy.

(v) Malpractice liability.

(vi) Documentation.

(vii) Quality assurance.

(viii) Continuing education.

(ix) Patient rights.

(3) Related anatomy and physiology (including age-related differences).

(4) Fundamentals of fluid balance and electrolyte balance (including age-related differences).

(5) Equipment and supplies used in the preparation and administration of IV therapy:

(i) Administration sets:

(A) Primary.

(B) Secondary or piggyback, saline lock, Y type administration with controlled volume, filters.

(ii) Needleless systems.

(iii) Venous access devices.

(iv) Infusion site preparation and site dressing materials.

(v) Infusion regulation systems (pumps and controllers).

(vi) Labels.

(vii) Hanging devices.

(6) Parenteral solutions and indications for use (isotonic, hypotonic, hypertonic).

(7) Infection control and safety issues:

(i) Transmission.

(ii) Types of infections:

(A) Local.

(B) Systemic.

(iii) Prevention measures.

(iv) Standard precautions.

(8) Insertion of peripheral short catheters (theory and lab):

(i) Equipment.

(ii) Site selection.

(iii) Site preparation.

(iv) Inserting the IV access device.

(v) Dressing the site.

(vi) Documentation.

(9) Administration, maintenance and monitoring of peripheral IV therapy (theory and lab):

(i) Focused assessment pertaining to IV therapy.

(ii) Calculating IV rate.

(iii) Terminology.

(iv) Drug compatibility.

(v) Drug information.

(vi) Methods/technique of administering IV medications/fluids.

(vii) Continuous and intermittent monitoring of IV medications/fluids.

(viii) Local complications and nursing interventions:

(A) Phlebitis/thrombosis.

(B) Infiltration/extravasation.

(C) Catheter displacement.

(D) Occlusion.

(E) Hematoma.

(F) Cellulitis.

(G) Local infection.

(ix) Systemic complications:

(A) Sepsis.

(B) Medication and fluid interactions.

(C) Allergic reactions.

(D) Embolism.

(x) Documentation.

(xi) Discontinuing a peripheral IV.

(10) Centrally and peripherally placed vascular access devices:

(i) Indications for centrally placed devices.

(ii) Disadvantages and advantages.

(iii) Placement of devices:

(A) Review anatomy.

(B) Usual sites.

(C) Types of devices:

(I) Tunneled.

(II) Nontunneled.

(III) Implanted ports.

(IV) PICC.

(iv) Insertion-related complications:

(A) Pneumothorax.

(B) Air embolism.

(C) Catheter malposition.

(D) Mediastinal injury.

(E) Hemothorax.

(F) Chylothorax.

(G) Hydrothorax.

(H) Brachial plexus injury.

(I) Arterial laceration.

(J) Extravascular malposition.

(K) Intravascular malposition.

(L) Pericardial tamponade.

(v) Long-term complications:

(A) Dislodgement.

(B) Air embolism.

(C) Local infection.

(D) Sepsis.

(E) Catheter migration.

(F) Catheter occlusion.

(G) Vessel thrombosis.

(H) Damaged catheter.

(I) Superior Vena Cava Syndrome.

(J) Skin erosion.

(vi) Maintaining central venous infusions (differentiate for types of access devices):

(A) Checking placement.

(B) Changing dressings.

(C) Changing IV tubing and solution.

(D) Changing catheter cap.

(E) Flushing.

(F) Administering primary or secondary infusion.

(G) Obtaining a blood sample.

(H) Determining intake and output.

(I) Documenting.

(11) Special considerations:

(i) Setting:

(A) Acute care.

(B) Home care.

(C) Long-term care.

(D) Ambulatory care.

(E) Hospice care.

(ii) Patient education.

(iii) Ethical/cultural issues.

(iv) Other—geographical practice setting differences.

[Pa.B. Doc. No. 10-773. Filed for public inspection April 30, 2010, 9:00 a.m.]

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# STATE REAL ESTATE COMMISSION

## [ 49 PA. CODE CH. 35 ]

## Seller Property Disclosure Statement

The State Real Estate Commission (Commission) proposes to add §§ 35.284a and 35.335a (relating to disclosures required by the Real Estate Seller Disclosure Law; and seller's property disclosure statement) to read as set forth in Annex A.

A. *Effective Date*

The regulations will be effective upon publication of the final-form regulations in the *Pennsylvania Bulletin*.

B. *Statutory Authority*

The regulations are proposed under the authority of section 7304(a) of the Real Estate Seller Disclosure Law (SDL) (68 Pa.C.S. § 7304(a)), and sections 404 and 604(a)(15.1) of the Real Estate Licensing and Registration Act (RELRA) (63 P. S. §§ 455.404 and 455.604(a)(15.1)).

C. *Background and Purpose*

Section 604(a)(15.1) of the RELRA (63 P. S. § 455.604(a)(15.1)) makes failing to provide a disclosure required by another law in connection with a real estate transaction a disciplinary offense. The SDL, which replaced the repealed Real Estate Seller Disclosure Act (SDA) (68 P. S. §§ 1021—1036), establishes disclosure duties on real estate licensees and sellers for certain types of residential real estate transfers and delineates specific aspects of the property that must be disclosed by the seller to a prospective buyer.

Specifically, section 7313(c) of the SDL (68 Pa.C.S. § 7313(a)) requires seller's agents to advise sellers of their responsibilities under section 7303 of the SDL (68 Pa.C.S. § 7303) and provide sellers with a property disclosure statement. Under the SDL, sellers are required to: disclose any known material defects to the buyer before signing an agreement of transfer by completing a property disclosure statement that meets or exceeds the requirements of section 7304 of the SDL (68 Pa.C.S. § 7304), deliver the completed property disclosure statement to buyers or buyers agent under section 7305 of the SDL (68 Pa.C.S. § 7305), and notify buyers of any inaccuracies in accordance with section 7307 of the SDL (68 Pa.C.S. § 7307).

Under section 7304(a) of the SDL, the Commission is required to promulgate a property disclosure statement that satisfies the requirements of subsection (b). Until that time, under subsection (c), the statement contained in the SDA satisfies the requirements of the SDL.

Having reviewed the SDA property disclosure statement for 5 years and determining that it satisfactorily reflected the requirements of the SDL, the Commission attempted to promulgate a final-form regulation, with proposed rulemaking omitted under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240), known as the Commonwealth Documents Law (45 P. S. §§ 1201 and 1202), that included the SDA property disclosure statement and specific duties on licensees as set forth in the SDL. On May 26, 2006, the Commission submitted the proposed-omitted final form regulations to the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC).

After extensive discussions with the HPLC, on June 7, 2006, the Commission tolled the review of the regulations under section 5.1(g)(1) of the Regulatory Review Act (71 P. S. § 745.5a(g)(1)), to allow it to make revisions to the text of the Annex recommended by the HPLC. Ultimately, after being requested by the HPLC to resubmit the regulations in proposed form, the Commission withdrew the regulations on June 13, 2006.

After that withdrawal, the Commission considered whether to further amend the previously submitted regulations and solicited comment from stakeholders. Following extended discussions at regularly scheduled meetings, the Commission voted to resubmit the regulations in proposed form. The proposed regulations are essentially the same disclosure form proposed in 2006. Two sections are rearranged to enhance clarity.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF NURSING
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7142

May 30, 2012

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Nursing
16A-5122: IV THERAPY FUNCTIONS FOR LICENSED PRACTICAL NURSES

Dear Chairman Lutkewitte:

Enclosed is a copy of a final rulemaking package of the State Board of Nursing pertaining to IV Therapy Functions for Licensed Practical Nurses.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Joseph J. Napolitano, PhD, MPH, CRNP, Chairperson
State Board of Nursing

JJN/CCS:rs
Enclosure
cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Carole Clarke Smith, Counsel
State Board of Nursing
State Board of Nursing

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-5122

SUBJECT: IV THERAPY FUNCTIONS FOR LICENSED PRACTICAL NURSES

AGENCY: DEPARTMENT OF STATE
STATE BOARD OF NURSING

**TYPE OF REGULATION**

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

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**FILING OF REGULATION**

| DATE | SIGNATURE | DESIGNATION |
|---|---|---|
| _____ | _____ | HOUSE COMMITTEE ON PROFESSIONAL LICENSURE |
| 5/30/12 | Michele Warren | MAJORITY CHAIR Julie Harhart |
| 5/30/12 | Mary Walmer | SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE |
| _____ | _____ | MAJORITY CHAIR Robt. M. Tomlinson |
| 5/30/12 | K Cooper | INDEPENDENT REGULATORY REVIEW COMMISSION |
| _____ | _____ | ATTORNEY GENERAL (for Final Omitted only) |
| _____ | _____ | LEGISLATIVE REFERENCE BUREAU (for Proposed only) |