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Issue LPNs; Series II; File 56

Juanita Hunter

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DATE: May 26, 1989

TO: BOARD OF DIRECTORS

FROM: Martha L. Orr, Executive Director

RE: Status of LPN/IV Therapy Regulations and Lawsuit - CONFIDENTIAL

The Association has been notified that our lawsuit against the Departments of Health and Education will be heard in Superior Court on June 7.

We have also received the enclosed draft of a revision of the regulations pertaining to LPN performance of intravenous procedures. Karen Ballard’s letters of further inquiry about the substance of the revision are also attached. We expect that this revision will be brought to the Code Committee of the State Health Planning & Review Council for information in June and for adoption in July.

In addition, I have enclosed a copy of a resolution which may be presented to the Board of Regents by the State Education Department. We do not yet have confirmation of that plan.

You will note that almost all of the Association’s objections to the regulations and to the process through which they were adopted have been addressed in the proposed revision and the resolution. However, since no official action has been taken as of this point, our legal counsel recommends that we proceed to the June 7th hearing as scheduled. Ideally, we would then get a confirmation of our legal standing to proceed to the merits of the lawsuit. I have concurred with this plan.

Please contact K. Ballard or myself if you have any questions or concerns about this matter.

MLD/ker

Enclosures

May 23, 1989

Dr. Milene Megel, Ph.D., RN
Executive Secretary
New York State Board for Nursing
State Education Department
Cultural Education Center
Albany, New York 12230

Dear Dr. Megel:

Executive and program staff of The New York State Nurses Association have had the opportunity to review the new proposed regulations for the practice of intravenous therapy by Licensed Practical Nurses in Article 28, 36 and 40 facilities. Generally, many of the concerns of this Association seemed to have been addressed. However, we will be contacting Mr. Thomas Hartman of the Department of Health to discuss whether or not a Health Facilities Memorandum is still being proposed in order to further clarify the intent of the regulations.

There are still a few questions which the New York State Nurses Association hopes that your Department can clarify. They are:

1. Since there are hospitals (Article 28) which have certified home health agencies and hospices as part of their structure, will the restrictions included in the language of the Article 36 and Article 40 regulations be extended to these CHHAS and hospices or will they be allowed to practice under the more permissive Article 28 language? NYSNA is particularly concerned in those instances where a CHHA is incorporated under the Article 28, not Article 36 provisions.

2. In this Association's earlier communication, we had requested that experimental/investigational drugs be prohibited in the practice of IV therapy for Licensed Practical Nurses. Since this language was not added, NYSNA would appreciate a statement from the State Board for Nursing regarding the role of LPNs in administering, either orally or intravenously, experimental/investigational drugs.
3. In addition, NYSNA would appreciate clarification as to whether albumin, which is often dispensed by pharmacies, will be considered for the purposes of these regulations to be a medication or blood product?

4. Finally, NYSNA believes that the question regarding whether or not it is within the scope of practice of a Licensed Practical Nurse to initiate anaphylaxis protocols still needs to be addressed.

The New York State Nurses Association's Board of Directors will be meeting on June 14th and 15th. At that time they will be reviewing in detail both the regulations and the proposed Board of Regents resolution. Your response to the above questions would facilitate the NYSNA Board's analysis and response. In addition, NYSNA's lawyer, Mr. George Harder will be in communication with Mr. Diaz regarding this matter.

Thank you for your consideration of these items and concerns.

Sincerely,

Karen A. Ballard, MA, RN
Director
Nursing Practice and Services

KAB/dpf
3. Will Licensed Practical Nurses be allowed to initiate anaphylaxis protocols?

Finally, NYSNA's greatest continuing concern is how these regulations will apply to certified home health agencies and, possibly, hospices which are part of an Article 28 facility and which may be incorporated under that facility and not the laws and regulations for Article 36 or 40 facilities? Is it the intent of these regulations to require compliance with the more permissive Article 28 regulations or the more restrictive Article 36/40 requirements? In reviewing the Regulatory Impact Statement, it appears that it is the intent of the Department of Health, the State Education Department and the State Board for Nursing to place specific controls over the home care setting. Therefore, it appears that a more restrictive interpretation would be appropriate.

Thank you for your consideration of these items and concerns.

Sincerely,

[Signature]
Karen A. Ballard, MA, RN
Director
Nursing Practice and Services

WHEREAS, the New York State Department of Health, through the State Hospital Review and Planning Council, promulgated regulations on January 18, 1988 permitting licensed practical nurses to perform intravenous therapy procedures in facilities under the jurisdiction of Public Health Law articles 28, 36 and 40, and

WHEREAS, said regulations were set forth at 10 NYCRR 400.15 and 10 NYCRR 700.4, and

WHEREAS, the Board of Regents and the State Education Department objected to said regulations as permitting the performance of services which exceed the scope of practice for the profession of licensed practical nursing, specifically in that said regulations permitted licensed practical nurses to provide total parenteral nutrition therapy, to perform intermittent flushing of intravenous therapy devices and to perform central venous line procedures in home-care settings, and

WHEREAS, the State Department of Health has concurrent jurisdiction over practice in facilities regulated by the Public Health Law but lacks the authority in the exercise of such jurisdiction to adopt regulations which are inconsistent with provisions of the Education Law, as interpreted by the Board of Regents, and

WHEREAS, the State Department of Health agreed to modify the regulations set forth at 10 NYCRR 400.15 and 10 NYCRR 700.4 following discussion and consultation with the State Education Department, and

WHEREAS, the State Department of Health has proposed to amend said regulations to accommodate the interpretation of the Board of Regents concerning Education Law 6902(2) and the scope of practice for the profession of licensed practical nursing, and

WHEREAS, the proposed amendments are consistent with the interpretation of the Board of Regents concerning the scope of practice for the profession of licensed practical nursing, in that they prohibit the performance of central venous line procedures by licensed practical nurses in home-care settings.

IT IS RESOLVED, that the proposal of the State Department of Health to amend the regulations set forth at 10 NYCRR 400.15 and 10 NYCRR 700.4 is hereby accepted, and

IT IS FURTHER RESOLVED, that the procedures permitted under said regulations, as amended, will be within the scope of practice for the profession of licensed practical nursing, as such is defined pursuant to Education Law 6902(2).
Regulatory Impact Statement
Licensed Practical Nurses and Intravenous Therapy Procedures

Statutory Authority

The authority for the promulgation of the subject regulations is contained in subdivision (2)(a) of section 2903, subdivision (5) of section 3612 and subdivision (4) of section 4010 of the Public Health Law, which authorizes the State Hospital Review and Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of Articles 28, 36 and 40 of the Public Health Law, and to establish minimum standards of operation for health care facilities and home health care agencies. The Commissioner is authorized in subdivision (6) of section 3612 to amend rules and regulations pertinent to standards of care of licensed home care services agencies.

Legislative Objective

The legislative objective of Articles 28, 36 and 40 of the Public Health Law includes the protection and promotion of the health of the inhabitants of the state through assuring the efficient provision of health services and standards of care of high quality.

Needs and Benefits

In January 1988, regulations describing the role of the licensed practical nurse (LPN) in intravenous (IV) therapy procedures were added to Parts 400 and 700 of 10 NYCRR. These regulations allow health care facilities and home care services agencies to assign intravenous therapy procedures to LPNs who have completed a training program, received supervised clinical experience and demonstrated competency in those procedures. The regulations were developed in conjunction with the New York State Board for Nursing.

Since the development of the regulations, there has been an increasing shift in the provision of health care services from the acute care hospital to primary health care and home health care settings. With the current prospective payment system based on diagnosis related groups, patients are experiencing shorter stays in hospitals and are being discharged home with need for continued health care services. Health care services provided in the home have become increasingly complex and include services such as chemotherapy, transfusion and intravenous therapy.

In light of the growing numbers and types of patients being treated at home and the rapid expansion of home health care services, there has been a growing concern, expressed by the State Board for Nursing, about regulatory oversight of LPNs performing IV therapy procedures in the home without on-site availability of physician or registered professional nurse (RN) supervision staff as would be found in hospital or nursing home settings.

The proposed regulations amend the current regulations by adding additional specific requirements in Section 700.4 of Part 700 that must...
The proposed regulations stipulate that before any home care service agency allows LPNs to perform IV therapy procedures in the home, each LPN must have satisfactorily completed a training program and supervised clinical experience in a general hospital. This information must be documented in the LPN’s personnel file.

Also in a home setting, a RN must initiate and monitor response to all new IV medications the patient receives in order to evaluate any adverse patient reaction to the medication.

The home care services agency must make arrangements for a registered professional nurse to be immediately available by phone in case the LPN needs additional information or assistance. That RN must be familiar with the patient’s medical condition and also knowledgeable about types of IV fluid and medication the patient is receiving.

The additional protections afforded by these proposed amendments have been endorsed by the State Board for Nursing and the Regents of the New York State Education Department.

Costs

The provision of IV therapy by LPNs in a home setting is an optional activity. If home care services agencies choose to allow LPNs to perform IV therapy procedures in the home, there may be costs associated with hospital training programs, back-up phone coverage by an RN and for the initial administration of new medications by the RN.

Paperwork

There will be no increase in the paperwork for home care services agencies.

Duplication

The proposed regulations for the governing the performance of IV procedures in the home by LPNs do not duplicate or conflict with any other regulations.

Alternatives

There is no alternative to this rule.
Regulatory Flexibility Analysis

The Role of the Licensed Practical Nurse in Intravenous Therapy Procedures

1) **Effect on Small Business**

Most home care services agencies are small businesses that will be affected by this regulation.

2) **Compliance Requirements**

The method of service delivery subject to this rule is optional, therefore, it does not impose an adverse economic impact or compliance requirement on small business.

3) **Professional Services**

In order to comply with the proposed rule, small businesses will need the services of a registered professional nurse to initiate and monitor all new medications the patient receives and to be available by telephone for consultation to the licensed practical nurse.

The small business will also need to arrange for professional services in a general hospital as the licensed practical nurse must complete the required training program and clinical experience for intravenous therapy in a general hospital.

4) **Compliance Costs**

The compliance costs would essentially be the same for small businesses as large businesses if the home care services agency decides to allow LPNs to perform IV therapy procedures. There may be costs associated with the hospital-based training programs for the LPNs who are learning about IV therapy procedures.

There will be costs associated with back-up phone coverage by the RN and for the initiation and monitoring of new medications by the RN.

5) **Minimizing Adverse Impact**

The approaches suggested in the New York State Administrative Procedures Act section 202-b(1) have been considered. The proposed rule was written to minimize economic impact by allowing for minimal operational and supervisory requirements which are consistent with the provision of quality services to patients at home.

6) **Small Business Participation**

Small businesses have been given an opportunity to participate in the development of the regulation as copies of the proposed regulation have been shared with interested parties and with the many industry trade organizations which actively represent home care services agencies.

3/8/89
Pursuant to the authority vested in the State Hospital Review and Planning Council by section 2803 of the Public Health Law, Subchapter A, of Chapter V of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is hereby amended to be effective upon publication of the Notice of Adoption in the State Register as hereinafter indicated.

Section 400.15 of Part 400 of Article 1 of Subchapter A of Chapter V of Title 10 is hereby AMENDED to read as follows:

400.15 The role of the licensed practical nurse in intravenous therapy procedures.

(a) For purposes of this section [only], facility shall mean [only] entity licensed [or certified] pursuant to Article[s] 28, 36 or 40 of the Public Health Law.

(b) [The] A facility may allow specially trained licensed practical nurses, under the supervision of a qualified registered professional nurse or physician, to perform all intravenous therapy procedures except for the administration of blood and blood products, intravenous chemotherapy, anti-neoplastic agents, and a bolus of medication by intravenous push [and certain other procedures involving central venous lines].

(c) The facility shall ensure that licensed practical nurses allowed to perform intravenous therapy procedures have satisfactorily completed a training program, received supervised clinical experiences and demonstrated competence in the performance of intravenous therapy procedures.

(d) The training program for intravenous therapy shall include at a minimum instruction in:

1. the facility's policies and procedures related to intravenous therapy.

2. the facility's quality assurance and risk management program.

3. anatomy and physiology related to intravenous therapy.

4. the solutions and drugs used in intravenous therapy, their pharmacological action and therapeutic effects.

5. procedures used for mixing intravenous medications and solutions.

6. the signs and symptoms, of complications and adverse reactions to intravenous therapy.

7. the functions, use and maintenance of intravenous devices and equipment; and

8. infection control techniques.

(e) The facility shall ensure that all intravenous therapy procedures performed by the licensed practical nurse are provided in
accordance with written policies and procedures (approved by the
nursing service, pharmaceutical service, administration, medical
director, or where applicable, the medical staff, and other
professional staff as needed. The facility shall ensure that policies
and procedures for intravenous therapy are developed, implemented and,
which are reviewed and updated as needed, but at least annually.

If the facility shall ensure that there is documentation in the
licensed practical nurse’s personnel file which indicates the training
program attended, number of hours and content of the program, supervised
clinical experiences and approval to perform intravenous therapy
procedures.

(g) Inservice education programs shall be conducted to update and
inform the licensed practical nurse of new intravenous therapy
procedures, equipment and medications (and to evaluate continued
competence). The programs shall be conducted as often as necessary but
at least on an annual basis and be documented in the personnel file of
the licensed practical nurse.

(h) The licensed practical nurse approved to perform intravenous
therapy procedures shall be under the direction of a registered
professional nurse.

Pursuant to the authority vested in the State Hospital Review and
Planning Council by sections 3612 and 6107 of the Public Health Law and
pursuant to the authority vested in the Commissioner of Health by
section 3612, subdivision (a), of the Public Health Law, Subchapter C,
of Chapter V of Title 10 (Health) of the Official Compilation of Codes,
Rules and Regulations of the State of New York, is hereby amended to
be effective upon publication of the Notice of Adoption in the State
Register as hereinafter indicated.

Section 700.4 of Part 700 of Article 1 of Subchapter C of Chapter
V of Title 10 is hereby AMENDED to read as follows:

700.4 The role of the licensed practical nurse in intravenous
therapy procedures.

(a) For purposes of this section only, a facility agency shall
mean any entity licensed or certified pursuant to Articles 25, 38,
or 40 of the Public Health Law.

(b) The facility agency may allow specially trained licensed
practical nurses, under the supervision of a qualified registered
professional nurse or physician, to perform all intravenous therapy
procedures except for the administration of blood and blood products,
intravenous chemotherapy, anti-neoplastic agents, and a bolus of
medication by intravenous push, and certain other procedures
involving central venous lines.

(c) In a home setting the home care services agency shall require
that:
(1) The licensed practical nurse satisfactorily complete a training program and supervised clinical experience in intravenous therapy procedures in a general hospital before being assigned to any intravenous therapy procedure in the home and be assigned to perform such procedures only for patients who are considered to be medically stable.

(2) A registered professional nurse initiate and monitor all new intravenous therapy medications the patient receives and continue to administer subsequent doses if it is determined to be necessary by the registered professional nurse.

(3) A registered professional nurse who is competent and knowledgeable about the administration of intravenous medications and familiar with the patient's condition be immediately available to the licensed practical nurses by telephone for consultation and

(4) Licensed practical nurses not be assigned to handle any central venous line procedure.

(5) The facility; agency shall ensure that licensed practical nurses allowed to perform intravenous therapy procedures have satisfactorily completed a training program, received supervised clinical experiences and demonstrated competence in the performance of intravenous therapy procedures.

(6) The training program for intravenous therapy shall include as a minimum instruction in:

(1) The facility's agency's policies and procedures related to intravenous therapy;

(2) The facility's agency's quality assurance and risk management program;

(3) Anatomy and physiology related to intravenous therapy;

(4) The solutions and drugs used in intravenous therapy, their pharmacological action and therapeutic effects;

(5) Procedures used for mixing intravenous medications and solutions;

(6) The signs and symptoms of complications and adverse reactions to intravenous therapy;

(7) The functions, use and maintenance of intravenous devices and equipment; and

(8) Infection control techniques.

(7) The facility agency shall ensure that all intravenous therapy procedures performed by the licensed practical nurse are provided in accordance with written policies and procedures approved by the nursing service, pharmaceutical service, administration, medical
The licensed practical nurse approved to perform intravenous therapy procedures shall be under the direction of a registered professional nurse.

3/23/89