

REGISTRAR'S SUBMISSION PACKAGE

**BOARD OF NURSING
18 VAC 90-20-10 et seq.**

Regulations Governing the Practice of Nursing

Analysis of Proposed Amendments to Regulation

1. Basis of Regulation:

Title 54.1, Chapter 24 and Chapter 30 of the Code of Virginia provide the basis for these regulations.

Chapter 24 establishes the general powers and duties of health regulatory boards including the power to establish qualifications for licensure and responsibility to promulgate regulations.

§ 54.1-3005 establishes the powers and duties of the Board of Nursing, including the duty to “*promulgate regulations for the delegation of certain nursing tasks and procedures not involving assessment, evaluation or nursing judgment to an appropriately trained unlicensed person by and under the supervision of a registered nurse, who retains responsibility and accountability for such delegation.*”

2. Statement of Purpose:

The purpose is to amend regulations pursuant to changes in the Code of Virginia made in Chapter 458 of the 1998 Acts of the Assembly which required the Board to promulgate regulations for the delegation of certain nursing tasks and procedures to unlicensed persons. In accordance with the second enactment clause, the Board promulgated emergency regulations that became effective on January 26, 1999. These proposed regulations replace the emergency regulations and are intended to establish those criteria which are necessary to protect the public health and safety in the delegation of some patient care to unlicensed persons.

3. Substance of Regulations:

18 VAC 90-20-300. Disciplinary provisions.

The proposed amendment adds a provision which includes in the list of actions constituting unprofessional conduct “delegating nursing tasks to an unlicensed person in violation of the provisions of 18 VAC 90-20-420.”

New Part VIII. Delegation of Nursing Tasks and Procedures.

18 VAC 90-20-420. Definitions.

Amendments provide the definitions for words and terms used in this part of the regulations as necessary for clarity and compliance. Those are “*delegation*”, “*supervision*”, and “*unlicensed person*”.

The definition of “*unlicensed person*” has been modified from the emergency regulation in response to public comment. Several persons and facilities interpreted the term to include licensed practical nurses, which was not the intent of the Board. To clarify the definition, another sentence was added to specify that, with the exception of a certified nurse aide, an “unlicensed person” does not include anyone licensed or certified by a board within the Department of Health Professions who is practicing within his recognized scope of practice.

18 VAC 90-20-430. Criteria for delegation.

The proposed amendments establish requirements for a plan for delegation to be adopted by the entity responsible for client care; set certain criteria which must be met in order for a nurse to delegate; state that the unlicensed person may not reassign the task or procedure; and establish that delegation may occur only after an assessment has been performed.

Comments on the emergency regulations requested that the Board consider specifying in regulation the various levels of supervision that must be incorporated into the institutional plan for delegation. The Board chose to allow each health care facility to develop its own plan for supervision provided it complies with the provisions of this section. It also amended subdivision 3 in subsection A to emphasize that the supervision must be sufficient to assure safe nursing care to meet the needs of the clients in their specific settings.

18 VAC 90-20-440. Assessment required prior to delegation.

This section establishes the requirements for an assessment and specifies those types of tasks which may be delegated to an unlicensed persons.

18 VAC 90-20-450. Supervision of delegated tasks.

The proposed regulation establishes the factors by which the nurse determines the method and frequency of supervision required; sets conditions under which another registered nurse may supervise the nursing tasks if the delegating nurse is not present; specifies what such supervision shall include; and establishes that an on-going assessment is necessary to determine if delegation continues to be appropriate.

Comment on the emergency regulation noted concern and confusion over the appropriate transfer of delegation from one registered nurse to another. To clarify the intent of the Board, the proposed amendment states that when the delegating nurse is not available, the delegation is either terminated or the authority to delegate is transferred to another registered nurse, who then becomes the delegating nurse with responsibility for the delegation.

18 VAC 90-20-460. Nursing tasks which shall not be delegated.

The proposed regulation establishes that nursing tasks that shall not be delegated are those which are inappropriate for a specific, unlicensed person to perform on a specific patient after an assessment is conducted; and it sets out certain nursing tasks which may not be delegated to any unlicensed person.

In response to comment, the board has changed the “may” to a “shall” in subsection B to read, “Nursing tasks that shall not be delegated to any unlicensed person are”.

4. Issues of the Regulations

ISSUE 1: Responsibility for making decisions on delegation.

An issue that precipitated the need for statutory authority to promulgate regulations on delegation was the question of a line of authority and who is responsible for making a decision to delegate certain tasks to unlicensed persons. Without regulations, there was no guidance for employers or for registered nurses who were occasionally asked to take responsibility for a delegation which they felt was inappropriate or dangerous to the patient. These regulations permit registered nurses, who are qualified by education and experience to supervise and coordinate the delivery of nursing care, to make decisions about the appropriate delegation of such care to others within the plan for delegation developed by the institution.

The plan for delegation must comply with provisions of the regulations and must provide for certain assessments, resources, and safeguards to be in place before delegation to unlicensed persons can occur within the institution. Therefore, the plan should include an assessment of the client population the institution serves, an analysis and identification of the nursing needs and priorities, organizational standards for sufficient supervision to ensure safe care in each specific setting, communication of the plan to staff, documentation of the training and competencies of unlicensed persons, and provisions for resources necessary to support safe delegation. Within that framework, it is also clearly stated that the delegation can only occur when, in the judgment of the registered nurse, it is appropriate and safe for the patient to do so.

In developing a plan for delegation, some institutions questioned the definition of an “unlicensed person” and had determined that it included a licensed practical nurse. In the adoption of proposed regulations to replace the emergency regulations, the Board clarified the definition .

ISSUE 2: Criteria for delegation.

The proposed regulations establish standards for the safe delegation of nursing care. The regulations describe the procedures for determining what task could be delegated and to whom and under what circumstances in order to adequately protect the public. In the concept paper by the National Council of States Boards of Nursing, the Five Rights of Delegation are described as: the right task, under the right circumstances, by the right person to the right person, with the right direction or communication, under the right supervision. Those Five Rights became the basis for the Board in establishing the criteria for delegation.

Foremost of the criteria is the responsibility and accountability of the registered nurse for the nursing care of the client. Regardless of an institutional plan, the delegating nurse must determine that

the task or procedure can be properly and safely performed by an unlicensed person and that the delegation does not jeopardize the patient. Delegation can only occur on a client specific basis with clear instructions for performance of the tasks with for expected outcomes. Delegation can also only occur when the unlicensed person has been clearly identified as such to the patient by nametag or in person by the delegating nurse.

ISSUE 3: Supervision of the unlicensed person to whom a task is delegated

Questions were raised about whether regulations should stipulate the levels of supervision as “immediate supervision”, “direct supervision”, and “indirect supervision” with specific parameters and practice settings described. The Delegation Advisory Committee reviewed regulations from other states and discussed at length the advantages and disadvantages of specifying levels of supervision. It recommended against adopting such a regulation. While it will be necessary and appropriate for an entity to include the level and degree of supervision required for delegation in each practice settings within that institution, the Board determined that it was not appropriate or necessary to so specify by regulation. Instead, the Board adopted regulations to provide those general requirements that are necessary for patient safety, and it directed the institutions to develop a plan that is suited to its patient population and their needs. An amendment was added to definitely state that the delegation plan shall provide “establishment of organizational standards to provide for sufficient supervision which assures safe nursing care to meet the needs of the clients in their specific settings.”

Criteria for supervision are clearly articulated by the proposed regulations, which state the factors that determine the method and frequency of supervision. Rather than prescribing supervision for every situation or every patient setting, the determination on the level and type of supervision is to be based on the stability and condition of the patient, the experience and competency of the unlicensed person, the nature of the tasks or procedures, and the proximity and availability of the registered nurse when the tasks in being performed. Proposed regulations also provide that delegation should either be terminated or the authority to delegate transferred to another registered nurse when the delegating nurse is no longer going to be available to supervise. Delegation then becomes the decision and responsibility of the new supervising nurse as the delegating nurse.

In addition to the factors that determine the method and frequency of supervision, the regulations also specify what constitutes appropriate supervision.

ISSUE 4: Tasks which may or may not be delegated.

As the National Council’s position paper states, nursing is a knowledge-based process and cannot be reduced to a list of tasks. Therefore, the Board did not attempt to specify what tasks or procedures may be delegated – such delegation is dependent on the factors stated in the Five Rights of Delegation and set forth in these regulations. However, the Board has specified the assessment of the patient and the unlicensed person that must be performed prior to a delegation. The delegating nurse must assess the clinical status and stability of the patient’s condition, determine the type, complexity and frequency of the nursing care needed and delegate only those tasks which meet the criteria set forth in regulation. The delegating nurse must also assess the training, skills and experience of the unlicensed person to determined which tasks are appropriate and the level of supervision that is needed.

In addition, there are types of nursing tasks which are always inappropriate and unsafe to be delegated, and those are prohibited by these regulations to be delegated to any unlicensed person.

Advantages or disadvantages

For the clients or patients in Virginia, there are clear advantages to a plan and criteria for delegation that establishes institutional standards and responsibility for delegation of unlicensed persons. In a changing health care system, there is a need for competent, appropriately supervised, unlicensed assistive personnel to enable institutions to deliver affordable, quality health care. Consumers are benefited by regulations which empower registered nurses to delegate certain tasks that are appropriate to a patient at a given time in a given setting and that are within the abilities of the unlicensed person and within the scope of the nurse's practice.

For the entities that need to employ such persons, these regulations provide requirements for a delegation plan which are sufficiently prescriptive to provide the necessary framework but flexible enough to allow the institution to craft a plan which meets the particular needs of its clients in the settings in which they receive nursing care.

For registered nurses and unlicensed persons, provisions for a delegation provide some assurance that the appropriate assessments have been made at the institutional level, the organization has provided for sufficient supervision, the necessary training and competencies have been identified and addressed, and the resources are available for appropriate delegation. With a plan and certain criteria in place, there is some structure and guideline for delegation for both the delegating nurse and the person to whom the task has been delegated.

For the agency, there are no advantages or disadvantages to the proposal other than the clarity the proposed regulations provide on the issue of appropriate delegation to unlicensed persons.

5. Estimated Fiscal Impact of the Regulations

I. Fiscal Impact Prepared by the Agency:

Number of entities affected by this regulation:

These regulations could potentially affect the 77,116 registered nurses licensed in Virginia. In addition, every facility, institution, agency, school system or any other entity that employs registered nurses and unlicensed persons could be affected by these regulations. The number of unlicensed persons to whom registered nurses would delegate certain tasks is unknown.

Projected cost to the agency:

The agency will incur some costs (less than \$5000) for mailings to the 1000 people on the Board's Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations. Every effort will be made to incorporate these into anticipated mailings and board meetings already scheduled.

It is also expected that a small number of licensees will be investigated for a reported violation, and some of those will result in a disciplinary case being opened. In those cases, costs would be charged back to the Board from the Investigative and Administrative Proceedings Division (APD) of the Department. Costs for

cases that do result in an informal conference committee proceeding (estimated to be less than 10 per year) would include travel expenses and per diem for board members as well as costs for the services of APD and Investigations. Informal conference committees typically hear several cases in a day, so the costs per case would be minimized.

Cost estimates for disciplinary cases related to the failure to comply with these regulations range from \$100 to cases resulting in pre-hearing consent orders to \$500 per case for those that result in an informal conference committee or a formal hearing. All expenses relating to enforcement of these regulations can be absorbed in the projected budget and existing employment level of the Board of Nursing and the Department of Health Professions.

Projected costs to the affected entities:

There would be no additional costs for compliance with these regulations for nurses or entities in the Commonwealth. The regulations provide guidance for an activity which is commonly practiced in various settings, that is the delegation of nursing tasks to unlicensed persons.

Citizen input in development of regulation:

In the development of the emergency regulations, a Delegation Advisory Committee was formed to solicit input from a number of individuals in addition to the members of the Board. The Committee met on three occasions and considered comment received on the draft regulations, which were put on the Board's web site and distributed to interested parties. With various parts of the Commonwealth, diverse nursing practices, and affected constituencies represented, the Committee brought an informed, balanced approach to rule-making and was able to achieve consensus on the regulations it recommended to the Board. The Board also held a public hearing on the draft emergency regulations and accepted and considered written comment prior to adoption.

A Notice of Intended Regulatory Action was published on 2/15/99 and was sent to persons on the board's public participation guidelines mailing list. Resulting comments were distributed to Board members and were considered in the adoption of proposed amendments to regulation. Public comment was also received at each meeting of the Board.

Localities affected:

There are no localities in the Commonwealth affected by these regulations.

II. Fiscal Impact Prepared by the Department of Planning and Budget:

(To be attached)

III. Agency Response:

The Board concurs with the economic impact analysis prepared by the Department of Planning and Budget.

c. Source of the legal authority to promulgate the contemplated regulation.

18 VAC 90-20-10 et seq. Regulations Governing the Practice of Nursing was promulgated under the general authority of Title 54.1 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
- 4. To establish schedules for renewals of registration, certification and licensure.*
- 5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*
- 6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 and Chapter 25 of this title.*
- 7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*
- 8. To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*
- 9. To take appropriate disciplinary action for violations of applicable law and regulations.*
- 10. To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the*

practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.

- 11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*
- 12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

Amendments to Chapter 30 of Title 54.1

The proposed regulations are being promulgated to comply with statutory provisions of House Bill 1055 (Chapter 458) of the 1998 General Assembly. These regulations are being promulgated as replacement for the Emergency Regulations mandated by a second enactment clause, which required the Board of Nursing to promulgate regulations to implement the act to be effective within 280 days of the enactment. (See attached copy of Chapter 458)

§ 54.1-3005. Specific powers and duties of Board.

In addition to the general powers and duties conferred in this title, the Board shall have the following specific powers and duties:

- 1. To prescribe minimum standards and approve curricula for educational programs preparing persons for licensure or certification under this chapter;*
- 2. To approve programs that meet the requirements of this chapter and of the Board;*
- 3. To provide consultation service for educational programs as requested;*
- 4. To provide for periodic surveys of educational programs;*
- 5. To deny or withdraw approval from educational programs for failure to meet prescribed standards;*
- 6. To provide consultation regarding nursing practice for institutions and agencies as requested and investigate illegal nursing practices;*
- 7. To keep a record of all its proceedings;*
- 8. To certify and maintain a registry of all certified nurse aides and to promulgate regulations consistent with federal law and regulation. Such regulations may include standards for the authority of licensed practical nurses to teach nurse aides;*
- 9. To approve programs that entitle professional nurses to be registered as clinical nurse specialists and to prescribe minimum standards for such programs;*
- 10. To maintain a registry of clinical nurse specialists and to promulgate regulations governing clinical nurse specialists;*
- 11. (Effective until July 1, 1999) To promulgate regulations for the voluntary certification of licensees as sex offender treatment providers. In promulgating such regulations, the Board shall consider the standards*

recommended by the Advisory Committee on Certified Practices pursuant to § 54.1-3610. The provisions of this subdivision shall expire on July 1, 1999;

12. To certify and maintain a registry of all certified massage therapists and to promulgate regulations governing the criteria for certification as a massage therapist and the standards of professional conduct for certified massage therapists; and

13. To promulgate regulations for the delegation of certain nursing tasks and procedures not involving assessment, evaluation or nursing judgment to an appropriately trained unlicensed person by and under the supervision of a registered nurse, who retains responsibility and accountability for such delegation.

d. Letter of assurance from the office of the Attorney General.

See attached.

e. Summary of Public Comment received in response to the Notice of Intended Regulatory Action.

The Notice of Intended Regulatory Action was published on, February 15, 1999 and subsequently sent to the Public Participation Guidelines Mailing List of the Board. Comments were made on the emergency regulations that are currently in effect and are being replaced with permanent regulations. There were five written comments considered by the Board, but no one spoke before the Board during the public comment time prior to adoption of proposed regulations.

One person commended the Board for the delegation regulations but requested more clarification on the definition of an “unlicensed person”. The licensed practical nurses at her hospital had been told that the delegation regulation applied to them.

One person requested that the Board consider using verbiage from a position paper by the Massachusetts Nurses Association.

A group of nine individuals at a convalescent center wrote to express agreement with the regulations.

The Director of Public Health Nursing for the Department of Health requested the following: a) inclusion of the levels of supervision in the section on definitions and an additional requirement that those levels be included in the employer’s plan for delegation; b) some sort of an approval process for the institutional plan for delegation; c) an amendment to clarify the roles of the delegating nurse and the supervising nurse if they are not the same person (if the nurse who made the original decision to delegate is not available and designates another nurse to supervise the unlicensed person); and d) an amendment to change the “may” to “shall” in section 460 to specify that certain tasks are not to be delegated to any unlicensed person.

The Virginia Nurses Association wrote to express the concerns of some of its members on the following issues: a) the definitions of the levels of supervision; b) permissive terminology in section 460 be amended to directive language; and c) question on whether there should be a maximum number of individuals to whom a nurse could delegate at anyone time. The VNA also commented that there should be latitude in writing regulations so that they remain *usable in the face of the dynamic nature of health care today.*

f. Changes to existing regulations.

18 VAC 90-20-300. Disciplinary provisions.

The proposed amendment adds a provision which includes in the list of actions constituting unprofessional conduct “delegating nursing tasks to an unlicensed person in violation of the provisions of 18 VAC 90-20-420.”

New Part VIII. Delegation of Nursing Tasks and Procedures.

18 VAC 90-20-420. Definitions.

Amendments provide the definitions for words and terms used in this part of the regulations as necessary for clarity and compliance. Those are “*delegation*”, “*supervision*”, and “*unlicensed person*”.

The definition of “*unlicensed person*” has been modified from the emergency regulation in response to public comment. Several persons and facilities interpreted the term to include licensed practical nurses, which was not the intent of the Board. To clarify the definition, another sentence was added to specify that, with the exception of a certified nurse aide, an “unlicensed person” does not include anyone licensed or certified by a board within the Department of Health Professions who is practicing within his recognized scope of practice.

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The proposed amendments establish requirements for a plan for delegation to be adopted by the entity responsible for client care; set certain criteria which must be met in order for a nurse to delegate; state that the unlicensed person may not reassign the task or procedure; and establish that delegation may occur only after an assessment has been performed.

Comments on the emergency regulation requested that the Board consider specifying in regulation the various levels of supervision that must be incorporated into the institutional plan for delegation. The Board chose to allow each health care facility to develop its own plan for supervision provided it complies with the provisions of this section. It also amended subdivision 3 in subsection A to emphasize that the supervision must be sufficient to assure safe nursing care to meet the needs of the clients in their specific settings.

18 VAC 90-20-440. Assessment required prior to delegation.

This section establishes the requirements for an assessment and specifies those types of tasks which may be delegated to an unlicensed persons.

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The proposed regulation establishes the factors by which the nurse determines the method and frequency of supervision required; sets conditions under which another registered nurse may supervise the nursing tasks if the delegating nurse is not present; specifies what such supervision

shall include; and establishes that an on-going assessment is necessary to determine if delegation continues to be appropriate.

Comment on the emergency regulation noted concern and confusion over the appropriate transfer of delegation from one registered nurse to another. To clarify the intent of the Board, the proposed amendment states that when the delegating nurse is not available, the delegation is either terminated or the authority to delegate is transferred to another registered nurse, who then becomes the delegating nurse with responsibility for the delegation.

18 VAC 90-20-460. Nursing tasks which shall not be delegated.

The proposed regulation establishes that nursing tasks that shall not be delegated are those which are inappropriate for a specific, unlicensed person to perform on a specific patient after an assessment is conducted; and it sets out certain nursing tasks which may not be delegated to any unlicensed person.

In response to comment, the board has changed the “may” to a “shall” in subsection B to read, “Nursing tasks that shall not be delegated to any unlicensed person are”.

g. Statement of reasoning for the regulations.

The proposed regulations authorize the registered nurse to delegate certain tasks not involving nursing assessment, evaluation or judgment but ensure that the registered nurse retains the responsibility and accountability for delegating appropriately. The proposal is necessary in that the delegation of certain aspects of nursing care is unavoidable to meet the public’s need for accessible, affordable, quality health care in today’s rapidly changing health care system and is already occurring in Virginia, yet registered nurses in Virginia have had no regulatory authority and guidance to delegate nursing tasks to others. Thirty-eight states reference delegation by registered nurses in their statutes or regulations.

This proposal results from deliberation by the Board since 1987. The Board concluded that the increasing use of unlicensed personnel requires that the registered nurse be involved in making decisions about the delivery of nursing care to protect the health, safety and welfare of the public. The Nursing Practice Advisory Committee to the Board, consisting of representatives from twenty nursing organizations, unanimously recommended to the Board that it pursue legislation, which resulted in the passage of House Bill 1055 by the 1998 General Assembly.

The legislation required the promulgation of emergency regulations which were essential to protect patients in the Commonwealth who, without their knowledge, may be receiving nursing treatment by persons who are not licensed by the Board of Nursing or licensed or certified by any health regulatory board within the Department. In the interest of public health and safety, the General Assembly mandated the Board to promulgate regulations establishing the conditions under which certain tasks or procedures could be delegated. In the words of the legislation, those tasks should not involve assessment, evaluation or nursing judgment and the unlicensed person should be appropriately trained for the specified tasks to be assigned. The registered nurse making the delegation is responsible for the supervision of the unlicensed person and retains responsibility and accountability for the delegation.

The emergency regulations, which were adopted by the Board to provide the guidance and framework for such delegation by the registered nurses in Virginia, became effective on January 26, 1999. These proposed regulations replace the emergency regulations and have been amended to clarify or further specify sections in which there were questions or comments.

In its development of proposed regulations, the Board used the premises set forth in a position paper on delegation published by the National Council of State Boards of Nursing. Among the principles it espouses, the white paper says that the delegation decision-making process must be based on the fundamental principle of protection of the health, safety and welfare of the patient and that any task represented as a nursing activity is the regulatory responsibility of the Board of Nursing. Since the Board holds the registered nurse accountable for the delegation of tasks and activities to unlicensed persons, these regulations are necessary to establish the conditions under which a delegation can occur, the criteria which must be met, the factors and principles behind a decision to delegate, and the type of supervision which must be provided.

h. Statement on alternatives considered.

The Board did not consider alternatives to the promulgation of regulations as it was mandated to do so by the statute. It did consider and did adopt the least burdensome regulation consistent with the specific provisions of the statutes and with its concern for public health and safety.

In an effort to determine what regulation would be essential to carry out the mandate of the statute and could also be understandable, enforceable, and most effective, the Board appointed an Advisory Committee on Delegation to research similar rules in other states and seek opinion from a wide range of settings where nursing services are provided.

The Committee was chaired by a Board member who is a registered nurse who provides home health services. Its membership included: a member of the Board who is a LPN, recently working in home health; a RN who is a representative of the Virginia Association of Home Care; a RN representing the Virginia Nurses Association; a RN representative of the Virginia Association of School Nurses; a Vice President in charge of patient care services at Danville Regional Medical Center, representing the Virginia Hospital and Health Care Association; a RN in a rehabilitation center, representing the Virginia Health Care Association; a RN who is a director of nursing at a hospital in Charlottesville, representing the Virginia Organization of Nurse Executives; a program head of nursing for a Patrick Henry Community College who also works as a staff nurse; a RN representing the Center for Quality Health Care Services & Consumer Protection in the Virginia Department of Health; a RN who works as a staff nurse in a physician's office; and representatives from the Department of Medical Assistance Services and the Department of Rehabilitation Services.

With various parts of the Commonwealth, diverse nursing practices, and affected constituencies represented, the Committee brought an informed, balanced approach to rule-making and was able to achieve consensus on the regulations it recommended to the Board.

In the development of regulations, the Committee reviewed the rules on delegation in all other states that have such regulations or legislation and examined the Position Paper on Delegation issued by the National Council of State Boards of Nursing. In particular, the regulations from Nebraska, Massachusetts, Ohio, Kentucky, Georgia, Colorado, Florida, and Washington were studied for applicable verbiage and

provisions. After several meetings to develop a draft, the regulations were sent to persons on the Board's Public Participation Guideline listing and put on the Website for the Department. Persons were invited to comment in writing or to present their comments to a Public Hearing which was held on July 21, 1998. After the Hearing and close of comment, the Committee reconvened to consider each comment given. In response to comment, several amendments were recommended by the Committee and presented to the Board for adoption at its meeting on September 22, 1998.

Emergency regulations became effective on January 26, 1999; the Board staff has tracked any questions or comments received since persons and entities began implementation. During the comment period following publication of the Notice of Intended Regulatory Action, several persons gave comment and suggestions, which were distributed to Board members for their consideration prior to adoption of proposed regulations. The alternatives suggested in the comments and the Board's response are as follows:

Define levels of supervision: The commenters suggested that the levels of supervision be defined as "immediate supervision", "direct supervision", and "indirect supervision" with specific parameters and practice settings described. The Delegation Advisory Committee had reviewed regulations from other states and had discussed at length the advantages and disadvantages of specifying levels of supervision. It recommended against adopting such a regulation. While it will be necessary and appropriate for an entity to include the level and degree of supervision required for delegation in each practice settings within that institution, the Board determined that it was not appropriate or necessary to so specify by regulation. Instead, the Board adopted regulations to stipulate those general requirements that are necessary in a delegation plan for patient safety, and it directed the institutions to develop a plan that is suited to its patient population and their needs. An amendment was added to definitely state that the delegation plan shall provide "establishment of organizational standards to provide for sufficient supervision which assures safe nursing care to meet the needs of the clients in their specific settings."

Approval of the delegation plan: The question was raised about who would approve the delegation plan. It is not the intention of the Board to create an approval process for every delegation plan at every hospital, nursing home, institution, clinic, school or any other institution that employs registered nurses who will delegate certain tasks to an unlicensed person. The Board has established the standards for such a plan, the criteria which must be met before delegation can occur, and certain prohibitions to delegation. A registered nurse who violates the provisions of these regulations is guilty of unprofessional conduct and may have disciplinary action taken against her license.

Transfer of delegation authority from the delegating nurse to the supervising nurse: Concerns were expressed about the authority of the nurse who would be asked to supervise an unlicensed person to whom tasks have been delegated by another nurse acting as the delegating nurse. What would happen if the nurse who now has the responsibility for supervision of the unlicensed person is not comfortable with their level of ability in performing the assigned tasks? The Board agreed that the delegating nurse and the supervising nurse should be the same person. Therefore, it amended the emergency regulation to provide that when the delegating nurse is not available, the delegation shall be terminated or the delegation authority transferred to another registered nurse who then becomes the delegating nurse. That person then assumes authority for the delegation and can make a new determination of its appropriateness based on the current conditions and factors as set forth in regulation.

Need for prescriptive rather than permissive language in tasks which should not be delegated: The Board agreed with commenters who stated that the prohibition on delegation of certain nursing tasks should be stated as "shall" not be delegated, rather than "may" not be delegated.

Limitation on the number of unlicensed persons to whom a registered nurse can delegate at any one time:

A question was raised about whether such a limit should be set, but the Board chose to rely on the criteria for delegation and supervision rather than on an artificial limit which would not be appropriate for every situation. If the number of unlicensed persons each nurse may supervise becomes a patient safety issue, the Board will revisit the issue.

Need for clarification of definition of an “unlicensed person”: It was reported to the Board that some institutions interpreted the definition of an unlicensed person to include a licensed practical nurse (LPN). Since LPN’s are licensed by the Board, there was no intention that they be considered “unlicensed” for the purposed of delegation by a registered nurse. To clarify the definition, the Board proposes that a sentence be added to specify that, with the exception of certified nurse aides, “unlicensed person” does not include anyone licensed or certified by a health regulatory board.

Consideration of regulations on delegation from Massachusetts: The Delegation Advisory Committee specifically reviewed regulations from Massachusetts as well as other states with such regulations. It also reviewed position papers adopted by nursing groups and incorporated those portions that it found applicable and appropriate.

The Board agrees with the statement made by the Virginia Nurses Association, “ We believe that there should be latitude in the writing of regulations so that the regulations can remain usable in the face of the dynamic nature of health care today. “ They also recommended that the regulations be prescriptive where possible to protect the public safety and to assist the registered nurses in their delegation. The Board has sought to establish such a balance in its proposed regulations on delegation.

i. Statement of clarity.

Prior to the adoption of emergency regulations by the Board, the Delegation Advisory Committee and the Board met on several occasions and discussed the changes in open sessions. Drafts regulations were widely distributed to interested parties while the emergency regulations were in development; comments were solicited and considered by the Committee and the Board in the promulgation process. The clarity and reasonableness of the language that was adopted had the approval of the registered nurses who represented various practice settings in all parts of the Commonwealth, the Assistant Attorney General who worked with the Board in drafting regulatory language, and members of the Board.

j. Schedule for review of regulation.

The proposed amendments to these regulations will be reviewed following publication in the Register and the 60-day public comment period. If there are any oral or written comments received during the comment period or at the Public Hearing, the Board will consider revisions to the proposal prior to adoption of final regulations.

Public Participation Guidelines of the Board of Nursing (18 VAC 90-10-10 et seq.) require a thorough review of regulations each biennium. Therefore, the Board will review this set of regulations in 2001 and will submit any recommended amendments for permission to publish.

In addition, the Board receives public comment at each of its meetings and will consider any request for amendments. Petitions for rule-making also receive a response from the Board during the mandatory 180 days in accordance with its Public Participation Guidelines.

k. Anticipated Regulatory Impact

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board of Nursing must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some costs (less than \$5000) for mailings to the 1000 people on the board's Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations. Every effort will be made to incorporate those into anticipated mailings and board meetings already scheduled.

It is also expected that a small number of licensees will be investigated for a reported violation, and some of those will result in a disciplinary case being opened. In those cases, costs would be charged back to the Board from the Investigative and Administrative Proceedings Division (APD) of the Department. Costs for cases that do result in an informal conference committee proceeding (estimated to be less than 10 per year) would include travel expenses and per diem for board members as well as costs for the services of APD and Investigations. Informal conference committees typically hear several cases in a day, so the costs per case would be minimized.

Cost estimates for disciplinary cases related to the failure to comply with these regulations range from \$100 to cases resulting in pre-hearing consent orders to \$500 per case for those that result in an informal conference committee or a formal hearing. All expenses relating to enforcement of these regulations can be absorbed in the projected budget and existing employment level of the Board of Nursing and the Department of Health Professions.

Projected cost on localities:

There is no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed registered nurses, unlicensed persons and the entities in which they are employed.

Estimate of number of entities to be affected:

These regulations could potentially affect the 77,116 registered nurses licensed in Virginia. In addition, every facility, institution, agency, school system or any other entity that employs registered nurses

and unlicensed persons could be affected by these regulations. The number of unlicensed persons to whom registered nurses would delegate certain tasks is unknown.