THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

DEPUTY COMMISSIONER FOR THE PROFESSIONS
Office of the Professions

[Practice Memorandum: 2001.2]

February 27, 2001

TO: Nurse Practitioners, Registered Professional Nurses, Pharmacists, and Physicians

FROM: Johanna Duncan-Poitier, Deputy Commissioner for the Professions

SUBJECT: **New Provisions of Law Concerning the Administration of Immunizations and Anaphylactic Agents by Registered Professional Nurses Utilizing Non-Patient Specific Orders and Protocols***

I am pleased to share with you information on the administration of immunizations and anaphylactic agents for non-patient specific orders and protocols. Before the new law was enacted, the authority under which a nurse administered immunizations was unclear. The new law was passed to clarify and officially authorize the important practice of providing immunizations to the people of New York State and establish appropriate standards of care. The accompanying information will help you become familiar with pertinent requirements of these regulations, especially as you initiate new immunization programs. The regulations developed by the State Education Department are related to **non-patient specific** orders and protocols for immunizations and anaphylactic treatment and supercede any standing orders and protocols for non-patient specific immunizations and anaphylactic treatment which you or your agency may have used in the past. These regulations do **not** affect **patient specific** orders and protocols for immunizations and anaphylaxis which you or your agency may currently use.

Some basic provisions addressed by the regulations, which became effective on September 19, 2000, include:

- Immunizing agents which may be used in each age category are specified in the regulations.
- Components required in all non-patient specific orders and protocols are detailed in the regulations.
- Some practitioners may now prescribe non-patient specific immunizations and anaphylactic agents.
- Some practitioners may also establish protocols according to regulations.
- Pharmacists now have special obligations regarding pertinent pharmaceutical agents, syringes and needles.

* Section 2166 of the Public Health Law and Sections 6527, 6909 and 6807 of the Education Law, Part 64.7 of the Regulations of the Commissioner of Education and Section 29 of the Rules of the Board of Regents

- There are new requirements for handling and storage of immunization and anaphylactic agents prescribed on a non-patient specific standing order.
- Failing to follow new rules and regulations regarding non-patient specific orders for immunization and treatment of anaphylaxis may result in misconduct charges.

Additional details are in the attached chart.

If you have any questions or concerns, please contact either the New York State Board for Nursing at (518) 474-3817 Ext. 120, New York State Board for Medicine at (518) 474-3817 Ext. 560 or the New York State Board for Pharmacy at (518) 474-3817 Ext. 130. You may also email:

NURSEBD@MAIL.NYSED.GOV
MEDBD@MAIL.NYSED.GOV
PHARMBD@MAIL.NYSED.GOV,

or you may write to the appropriate professional board office (as noted above), New York State Education Department, Office of the Professions, State Education Building—Second Floor, 89 Washington Avenue, Albany, NY 12234-1000.

Attachment

OFFICE OF THE PROFESSIONS

NON-PATIENT SPECIFIC IMMUNIZATIONS AND ANAPHYLAXIS

CONTENTS

	Pag
Information for Registered Professional Nurses	1
CPR Requirements	1
Immunizing Agents	1
Administration of Immunizations	1
Epidemics	1
Registered Professional Nurse Obligations	2
Protocol Requirements	2
Anaphylaxis Administration Requirements	2
Anaphylaxis Protocol	3
Professional Misconduct Implications	3
Information for Licensed Practical Nurses	3
Information for Pharmacists	3
Prescriber Obligations	4

NON-PATIENT SPECIFIC STANDING ORDER AND PROTOCOL GUIDELINES

INFORMATION FOR REGISTERED PROFESSIONAL NURSES

CPR

All RNs involved in the administration of immunizing agents in accordance with a non-patient specific standing order and protocol must be currently certified in CPR by the American Red Cross, American Heart Association or an equivalent organization acceptable to the Department.

IMMUNIZING AGENTS

- The list of authorized immunizing agents differs for adults and children. Adults are persons who are 18 years of age or older; children are persons under 18 years of age. The agents are:
- Adults: Hepatitis A, Hepatitis B, Influenza, Pneumococcus, Meningococcus, Diphtheria, Tetanus, Measles, Mumps, Rubella, Varicella, Inactivated Polio, and any additional agents approved by the Board of Regents.*
- Children: Diphtheria, Tetanus, Acellular Pertussis, Measles, Mumps, Rubella, Varicella, Haemophilus Influenza Type b (HIB), Inactivated Polio, Hepatitis B, and any additional agents approved by the Board of Regents.*

ADMINISTRATION OF IMMUNIZATIONS

- The non-patient specific standing order and protocol must be authorized by a physician or a certified nurse practitioner.
- RNs must maintain or ensure that a copy of the standing order(s) and protocol(s) authorizing them to administer immunizations is maintained.
- All RNs immunizing children in accordance with non-patient specific standing orders and protocols must be employed by, or act as an agent of, the Visiting Nurses Association or an equivalent organization legally authorized to provide nursing services as determined by the New York State Education Department <u>or</u> by a State, county, municipal or other government agency.

EPIDEMICS

Any RN who is CPR certified may administer any immunizing agent that is authorized by a non-patient specific standing order and protocol as part of an immunization program authorized, maintained or under the auspices of the State Commissioner of Health, a county commissioner of health, or a county public health director when the immunization program is instituted as a result of an epidemic declared by any of these public health officials.

*The Board of Regents may add immunizing agents in accordance with the recommendations of the Centers for Disease Control and Prevention and the New York State Department of Health.

REGISTERED PROFESSIONAL NURSE OBLIGATIONS

PROTOCOL REQUIREMENTS

- Ensure that the potential recipient is assessed for contraindications to immunizations;
- Inform each potential immunization recipient of the potential side effects and adverse reactions, orally and in writing, prior to immunization and inform each potential immunization recipient, in writing, of the appropriate course of action in the event of an untoward or adverse event. Vaccine Information Statements (VIS), developed by the Centers for Disease Control and Prevention (CDCP), United States Health and Human Services are recommended for this use.
- Obtain consent for the immunization from the potential recipient, or from a person legally responsible in the case of a minor or otherwise incapable person, before the immunization is administered.
- In cases of minors and persons incapable of personally consenting to immunization, consent may be gained by informing the legally responsible person of the potential side effects and adverse reactions in writing and obtaining a written consent prior to administering the immunization.
- Provide to each legally responsible immunization recipient, a signed certificate of immunization noting the recipient's name, date of immunization, address, immunization agent, administering nurse, immunizing agent, manufacturer and lot number, and recommendations for future immunizations.
- Communicate the information provided to the recipient to the recipient's primary care provider (PCP) if there is one.
- Have available on site, agents to treat anaphylaxis including, but not limited to, epinephrine and necessary needles and syringes.
- Report all adverse immunization outcomes to the Vaccine Adverse Reporting System (VAERS) using the appropriate form, from the Centers for Disease Control and Prevention, United States Department of Health and Human Services.
- Ensure that the record of all persons immunized includes: the non-patient specific standing order and protocol utilized, recipient's name, date, address of immunization site, immunizing agent, manufacturer and lot number of administered vaccine(s) and recommendations for future immunizations.
- Ensure that a record is kept of all potential recipients, noting those who refused to be immunized.

ANAPHYLAXIS ADMINISTRATION REQUIREMENTS

- Non-patient specific standing orders and protocols must be authorized by a physician or a certified nurse practitioner.
- RNs must maintain or ensure the maintenance of a copy of the standing order(s) and protocol(s) authorizing them to administer anaphylactic treatment agents..

REGISTERED PROFESSIONAL NURSE OBLIGATIONS (continued)

ANAPHYLAXIS PROTOCOL

- Ensure that a record is kept of all persons who received epinephrine and/or other agents to treat anaphylaxis including, but not limited to: the non-patient specific standing order and protocol utilized, the recipient's name, date, address of administration site, administering nurse, and anaphylactic treatment agent administered and its manufacturer and lot number.

- Arrange for appropriate follow up by contacting the local emergency medical services system (EMS) following administration of anaphylactic treatment agent(s), or ensure that equivalent follow up is provided through other arrangements. Report to EMS or other follow up care providers which anaphylactic treatment agent(s) was administered, the time administered, the dose, strength and route of administration.

- Report noted information regarding administration of agents to treat anaphylaxis to the recipient's primary care practitioner/provider, unless unable to obtain this information from the patient.

PROFESSIONAL MISCONDUCT

Professional misconduct in the practice of nursing and in the administration of immunizations and/or anaphylactic treatment agents following non-patient specific standing orders and protocols will include but is not limited to:

- Failure to adhere to any requirement prescribed in section 64.7 of the Regulations of the Commissioner of Education (refer to accompanying regulations).

- Administering an immunizing and/or anaphylactic treatment agent after the expiration date noted on the agent's label.

- Failure to store immunizing and/or anaphylactic treatment agents in accordance with directions on the label and official compendium of commonly known practices.

INFORMATION FOR LICENSED PRACTICAL NURSES

Licensed practical nurses (LPNs) are not authorized by this law to participate in administration of non-patient specific orders.

INFORMATION FOR PHARMACISTS

- Syringes and needles needed for administration may be provided to RNs. The sale of these immunization agents and needles and syringes may be considered a wholesale transaction. A wholesale registration from the State Board for Pharmacy will not be necessary for either of these transactions.

PRESCRIBER OBLIGATIONS

Non-patient specific standing orders for immunizations must contain the following:

EITHER

- Language authorizing RNs to administer immunizations;
- Name(s) and license number(s) of RNs individually authorized to administer the prescribed immunizations; or the name of the entity legally authorized to employ or contract with RNs to provide nursing services including administering prescribed immunizations thus eliminating the need to name all RNs individually.
- Language authorizing RNs to administer immunization(s) or anaphylactic agent(s).
- Names and license numbers of RNs individually authorized to administer prescribed medications.

OR

- Name of the entity which is legally authorized to employ or contract with RNs to provide nursing service of immunizations and anaphylactic treatment.
- A statement that RNs not individually named may administer immunization or anaphylactic treatment agents only within the employment or contract situation identified in the standing order.
- The specific immunizing agents that the RNs are authorized to administer.
- The period of time that the order is effective including beginning and ending dates.
- A protocol prescribing actions to be taken by an RN when administering immunizations in accordance with the non-patient specific standing order.
- The name, license number and signature of the prescribing physician, or certified nurse practitioner.
- Records of medications provided must be maintained for six years or as otherwise provided by law.