



STATE OF NEW YORK DEPARTMENT OF HEALTH

433 River Street, Suite 303
Troy, New York 12180-2299

March 5, 2007
DPACS: 07-06

Dear Chief Executive Officer:

On November 2, 2006, a letter was sent to all hospitals regarding the immunization of hospital inpatients 65 years of age and older against influenza and pneumococcal disease. This letter is being written to advise facilities of clarifications to the previous letter and supersedes that letter. The changes include:

- Written consent using a consent form is not required for the use of non-patient specific standing orders. Therefore, verbal consent is acceptable.
- When using non-patient specific standing orders, the fact that verbal or written consent has been obtained must be documented. This information may be included in a documentation/consent form, or may be documented in a notation in the patient's medical record.
- A patient specific order may be authorized by the patient's treating practitioner at any time during the hospital stay. Such patient specific orders may be carried out under the general hospital consent and no separate verbal or written consent would be required.
- Clarification has been added to the attached non-patient specific standing order sample protocols specifying that both influenza and pneumococcal vaccines can be given if a history of vaccination is not available.

On July 26, 2006, Governor Pataki signed into law amendments to Public Health Law that will now require hospitals to offer vaccinations to patients 65 years of age or older who are admitted to the hospital (copy enclosed). The law became effective on October 24, 2006.

The law requires hospitals to adopt an immunization policy that meets the provisions outlined in this correspondence. In addition, the law authorizes hospitals to implement a non-patient specific standing order policy for eligible patients in accordance with the immunization policy approved by the hospital. Hospitals should take steps immediately to implement these requirements and to secure supplies necessary to meet patient needs. The provisions of the law are outlined below and it is not expected that separate regulations will be promulgated at this time.

Immunizations Required

All immunizations given pursuant to this legislation should be in accord with the current recommendations of the Advisory Committee on Immunization Practices (ACIP). The current ACIP recommendations for pneumococcal vaccination date from 1997. Current ACIP recommendations for influenza vaccination are published each year prior to the start of influenza season.

- Influenza – Annually between September first and April first, all patients age sixty-five or older should be considered as candidates for vaccination against the influenza virus.

Current ACIP recommendations for influenza vaccination are found at <http://www.cdc.gov/mmwr/PDF/rr/rr5510.pdf>.

- Pneumococcal – All patients age sixty-five or older at any time of the year should be screened to identify those patients who are candidates for vaccination, including those patients who are candidates for a second dose. A second dose of pneumococcal vaccine is recommended if the patient received vaccine >5 years previously and was aged <65 years at the time of vaccination. Current ACIP recommendations are found at: <http://www.cdc.gov/mmwr/PDF/rr/rr4608.pdf>.

Affected Individuals

- The law specifies that all patients age 65 or older admitted to the hospital should be considered a potential candidate for immunization against influenza and pneumococcal disease.
- The law applies to hospital inpatients and as such would not mandate a similar program for hospital outpatients whose length of stay at the facility is less than 24 hours. Hospitals may, however, expand the program to identify other at-risk populations to whom immunizations may be offered.
- The hospital is expected to adopt an immunization policy that includes a clinical protocol for screening patients to identify those patients who are candidates for immunization. All candidates determined suitable for vaccination should be offered immunizations against influenza virus and pneumococcal disease.

Determination of Suitability for Vaccination

All persons eligible for vaccination by virtue of age and vaccination history should be deemed to be suitable for vaccination and offered vaccination, unless:

- The specific immunization is medically contraindicated for that individual according to the contraindications set forth in the ACIP recommendations or in the vaccine package insert.
- The patient confirms that he/she has received such vaccinations or is not in need of a second dose of vaccine against pneumococcal disease.

No patients should be vaccinated if the patient refuses the vaccine after being fully informed of the health benefits and risks of vaccination.

Each patient's record should include evidence that he/she has been screened to determine if he/she is a candidate for immunization. For patients who are not candidates for immunization, each patient's record should document the reason the vaccine was not administered to the patient.

Immunization Policy

Hospitals shall adopt an immunization policy for influenza and pneumococcal disease that includes but is not limited to:

- Procedures for the offering of immunizations against the influenza virus, between September first and April first, and pneumococcal disease during the admission or before discharge, to patients who are age sixty-five or older.
- A clinical protocol to identify those patients age sixty-five or older who are candidates for immunization. The protocol must include, but is not limited to, an assessment for contraindications to immunization. Facilities may expand the protocol to identify other at-risk populations to whom immunization should be offered.
- Provisions to notify all members of the hospital's medical staff of the immunization requirements, the option for a patient specific order for immunization, or, in the absence of a

patient specific order, the hospital's non-patient specific standing order policy for vaccination against influenza virus and pneumococcal disease for each admitted patient age sixty-five or older.

- Procedures for ensuring that individuals offered immunization or their representative receive information regarding the risks and benefits of vaccination. Vaccine Information Statements (VISs) developed by the Centers for Disease Control and Prevention (CDC), United States Health and Human Services, are required for this use and are found at the following websites: <http://www.cdc.gov/nip/publications/VIS/vis-facts.htm>
<http://www.immunize.org/vis/>
- A non-patient specific standing order policy authorized by the hospital's medical director or other responsible physician that provides for a nursing assessment by a registered professional nurse to determine the suitability of the patient for immunization, including, but not limited to, an assessment for contraindications to immunization.
- A system for documenting patient refusals, medical contraindications and any post-vaccination adverse events, in the patient's record.
- A system for documenting vaccine administration. A certificate of immunization should be provided to the patient with the following information documented for the patient and in the patient's medical record:
 - Which immunizing agent and VIS was given
 - Date of publication of VIS
 - Date VIS was given to the patient
 - Name and title of person administering vaccine
 - Date of administration
 - Vaccine manufacturer and lot number

This information may be included in a documentation/consent form to meet patient needs.

- Provisions for ensuring that, in accordance with the New York State Education Department NYSED nursing practice regulations (<http://www.op.nysed.gov/immunguide.htm>), verbal or written consent has been obtained and is documented in the patients record, whenever vaccination is administered utilizing non-patient specific orders.
- Provisions to document in the patient's record that the vaccination was refused. The patient and/or the patient's representative may refuse immunization upon being fully informed as to the risks and benefits of the immunizing agent(s).

Patient Specific Orders

- A patient specific order may be authorized by the patient's treating practitioner at any time during the hospital stay. Such patient specific orders may be carried out under the general hospital consent and no separate verbal or written consent would be required. It is expected that each patient or patient representative would receive documentation of immunization including the Vaccine Information Statements (VISs) developed by the Centers for Disease Control and Prevention (CDC).
- Patient specific orders indicating that the patient should not be vaccinated due to valid medical contraindications would take precedence over the hospital's non-patient specific standing order policy.

Non-Patient Specific Standing Orders

- In the absence of a patient specific order, the law authorizes facilities to utilize non-patient specific standing orders for patients who have been assessed by a registered professional nurse

to determine the suitability of the patient for immunization, including, but not limited to, an assessment for contraindications to immunization.

- Non-patient specific standing orders for immunization should be used only with a clinical protocol implemented to identify those patients who are candidates for immunization. The policy for implementing non-patient specific standing orders and the clinical protocol must be authorized by the medical director or other responsible physician.
- Verbal or written consent must be documented when immunizations are administered in accordance with a non-patient specific order.

Vaccine Availability

- The law allows the commissioner to waive these requirements if there is a shortage or delay in distribution of influenza and/or pneumococcal vaccine. If vaccines are not available due to shortages or unavailability, it should be noted in the patient's record why the vaccine was not offered.
- It is recognized that the influenza vaccine may not be readily available in early fall. In cases where the vaccine has not yet been received, the patient's record should note the reason the vaccine was not offered.

The requirements set forth in law support the recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP), which constitute the standard of medical care. By providing seniors with the opportunity to receive vaccinations as inpatients, the immunization rate in New York will increase, thus reducing the significant risks posed by influenza and pneumococcal disease to this population.

Any questions regarding this letter may be directed to the Department's Immunization Program at (518) 473-4437 or the Division of Primary and Acute Care Services at (518) 402-1003.

Sincerely,

Guthrie S. Birkhead, M.D., M.P.H.
Director
Center for Community Health

Martin J. Conroy
Director
Division of Primary & Acute Care Services