

**Template Non-Patient Specific Standing Orders and Protocol for Pharmacists
Administering Influenza, Pneumococcal and Meningococcal Vaccinations to Adults:
effective dates
beginning xx/xx/xxxx and ending xx/xx/xxxx**

In accordance with New York State Education Law Section 6801 and implementing New York State (NYS) Department of Education regulations codified at 8 N.Y.C.R.R. 63.9, I am prescribing this standing (non-patient specific) order and protocol. Licensed pharmacists employed by or under contract with _____ and possessing a certificate of administration issued by NYS Department of Education are authorized to administer to patients 18 years of age or older the influenza vaccines (both live attenuated and inactivated), pneumococcal vaccines, meningococcal vaccines and anaphylaxis treatment agents for the emergency treatment of anaphylaxis, as set forth below. Pharmacists must follow all applicable laws and regulations.

Each certified pharmacist administering vaccinations pursuant to this order and protocol shall comply with regulations specific to pharmacist administration of vaccines found at <http://www.op.nysed.gov/prof/pharm/part63.htm>.

These pharmacists are authorized to administer the influenza, pneumococcal and meningococcal vaccines and anaphylaxis treatment agents only while employed by or under contract with _____.

Non-Patient Specific Orders for:

A. Influenza Vaccine:

1. Administer inactivated seasonal influenza vaccine (IIV) 0.5ml intramuscular (IM) injection:

- **Inactivated Influenza Vaccine, Quadrivalent (IIV4),**
- **Inactivated Influenza Vaccine, Trivalent (IIV3) standard dose**
 - a. To all persons 18 years of age and older who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications and precautions to seasonal influenza vaccine, which include: history of a serious allergic reaction to a component of the vaccine (specific concern re: egg protein or latex) or a prior dose.
 - b. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.
- **Administer Inactivated Influenza Vaccine, Trivalent (IIV3) high dose formulation**
 - a. To all persons 65 years of age and older who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications and precautions to seasonal influenza vaccine, which include: history of a serious allergic reaction to a component of the vaccine (specific concern re: egg protein or latex) or a prior dose.
 - b. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.

2. **Pregnant women should receive seasonal inactivated influenza vaccine (IIV3 or IIV4) from a single dose vial or pre-filled syringe if it is available.**
 - a. If seasonal influenza vaccine from a single dose vial or prefilled syringe is not available, obtain verbal consent to administer thimerosal containing seasonal IIV to the pregnant woman and document this in the record.
 - b. If consent cannot be obtained for thimerosal containing vaccine, do not vaccinate with thimerosal containing vaccine.
3. **Administer Recombinant Seasonal Influenza Vaccine, Trivalent (RIV3) 0.5 mL intramuscular (IM) injection** to all patients aged 18 through 49 years who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications and precautions to seasonal influenza vaccine which include: history of a serious allergic reaction to a component of the vaccine or a prior dose. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy. If the person in the indicated age group has a history of serious allergic reaction to egg protein, they may be given RIV3, or referred to a physician with expertise in the management of allergic conditions for vaccination.
4. **Administer Cell-culture-based Seasonal Influenza Vaccine, Trivalent, (ccIIV3) 0.5mL intramuscular (IM) injection** to all patients aged 18 years and older who have provided consent and do not fail the assessment, as per the incorporated protocol. Persons will be screened for contraindications and precautions to seasonal influenza vaccine, which include: history of a serious allergic reaction to a component of the vaccine (specific concern re: egg protein and latex) or a prior dose. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.
5. **Administer Seasonal Influenza Vaccine, Trivalent (IIV3) 0.1ml intradermal (ID) injection**, via single-dose prefilled microinjection system, as per the manufacturer's instructions, to all persons 18 through 64 years of age who have provided consent and do not fail the assessment, per the incorporated protocol. The person will be screened for contraindications to seasonal influenza vaccine which include: serious allergic reaction to a vaccine component (specific concern re: egg protein) or history of a serious allergic reaction to a prior dose. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.
6. **Administer Seasonal Live-Attenuated Influenza Intranasal Vaccine, Quadrivalent, (LAIV4) 0.2 ml**, 0.1 ml sprayed in one nostril followed by 0.1ml sprayed in other nostril x1 to all persons 18 through 49 years of age who have provided consent and do not fail the assessment, per incorporated protocol. The person will be screened for contraindications to seasonal influenza vaccine which include: serious allergic reaction to a vaccine component (specific concern re: egg protein) or history of a serious allergic reaction to a prior dose. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. If the person has a nasal congestion serious enough to make breathing difficult, give IIV instead. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy. Consent and Screening questions will be reviewed for contraindications to LAIV4.

If answer of yes is given to any of these questions below then IIV should be given. If answers to the following questions are all no then the intranasal may be given.

- a. Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorders?
- b. Does the person to be vaccinated have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as steroids, or cancer treatment with x-rays or drugs?
- c. Is the person to be vaccinated receiving aspirin therapy or aspirin containing therapy and under the age of 19?
- d. Is the person to be vaccinated in close contact with someone who is severely immunocompromised (such as someone in a bone marrow transplant unit of a hospital)?
- e. Does the person to be vaccinated have certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems, or a history of Guillain-Barré Syndrome (GBS)?
- f. Has the person to be vaccinated received any other live virus vaccination in the past 28 days, such as MMR (Measles-Mumps-Rubella vaccine) and varicella?
- g. Is the person pregnant or could become pregnant within the next month?
- h. Has the person taken influenza antiviral medications, including Tamiflu® (oseltamivir phosphate) or Relenza (zanamivir), within the past 48 hours?

If LAIV4 0.2 ml is unavailable or refused, administer IIV 0.5ml IM or 0.1 ml ID.

B. Pneumococcal Vaccine

1. Administer pneumococcal conjugate vaccine (PCV13) 0.5 ml intramuscular (IM) injection to all adults aged 18 years and older with an indication for PCV13, who have not previously received PCV13 and who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications to PCV13, which include: serious allergic reaction to a vaccine component or history of a serious allergic reaction to a prior dose. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.

- a. Persons aged 18 years and older with the following conditions should receive vaccination with a single dose of PCV13:
 - Cerebrospinal fluid leak
 - Cochlear implant
 - Functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - Immunocompromising condition (e.g., HIV infection, congenital immunodeficiency, hematologic and solid tumors)
 - Organ or bone marrow transplantation
 - Chronic renal failure or nephrotic syndrome
 - Immunosuppressive therapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids, radiation therapy)
- b. Persons vaccinated with PCV13 should receive pneumococcal polysaccharide vaccine (PPSV):

- i. If the person has no history of pneumococcal polysaccharide vaccination, administer PCV13. A dose of PPSV should be administered at least 8 weeks later. Patients requiring additional doses of PPSV should follow the order and protocol below (See B2c).
 - ii. If the person has already received at least one dose of PPSV, then PCV13 should be administered at least one year after the last dose of PPSV. If patients require additional doses of PPSV, they should be administered at least 8 weeks after the last dose of PCV13 and at least 5 years after the last dose of PPSV.
 - iii. PPSV and PCV13 should not be administered at the same visit.
2. **Administer PPSV 0.5ml IM or subcutaneous (SC) injection** to all persons 18 years of age and older with an indication for PPSV who have not previously received PPSV and who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications to PPSV which include: serious allergic reaction to a vaccine component or history of a serious allergic reaction to a prior dose. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.

a. Indications for PPSV include:

- i. Persons 65 years of age or older with no or unknown history of prior receipt of PPSV
 - ii. Persons age 18-64 years with no or unknown history of prior receipt of PPSV and any of the following conditions:
 - Cigarette smoker
 - Chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
 - Chronic pulmonary disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma)
 - Diabetes, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
 - Functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - Immunocompromising condition (e.g., HIV infection, congenital immunodeficiency, hematologic and solid tumors)
 - Immunosuppressive therapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids, radiation therapy)
 - Organ or bone marrow transplantation
 - Chronic renal failure or nephrotic syndrome
 - Candidate for or recipient of cochlear implant
- b. If both PPSV and PCV13 are indicated in a person seeking vaccination (see also B1a), a single dose of PCV13 should be administered first.
 - i. Persons aged 18 years and older with the following conditions should receive vaccination with both PPSV and PCV13
 - Cerebrospinal fluid leak
 - Cochlear implant
 - Functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - Immunocompromising condition (e.g., HIV infection, congenital immunodeficiency, hematologic and solid tumors)
 - Organ or bone marrow transplantation

- Chronic renal failure or nephrotic syndrome
 - Immunosuppressive therapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids, radiation therapy)
- ii. If PCV13 is unavailable, one dose of PPSV should be given now. A dose of PCV13 should be given at least one year following the dose of PPSV. If additional doses of PPSV are required they should be given at least 8 weeks after the last dose of PCV13 and at least 5 years after the last dose of PPSV.
- c. The following adults require an additional dose of PPSV, if the recipient meets one of the following criteria:
- i. Persons 65 years of age or older and received prior PPSV vaccination before age 65 years, if five or more years have elapsed since their most recent dose.
 - ii. Persons 18-64 at highest risk for serious pneumococcal infection or likely to have a rapid decline in pneumococcal antibody levels, who require an additional dose of PPSV, administered at least five years after the first dose, including persons with the conditions:
 - Functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - Immunocompromising condition (e.g., HIV infection, congenital immunodeficiency, hematologic and solid tumors)
 - Organ or bone marrow transplantation
 - Chronic renal failure or nephrotic syndrome
 - Immunosuppressive therapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids, radiation therapy).

C. Meningococcal Vaccine

1. Administer meningococcal conjugate vaccine (MCV4) 0.5 ml intramuscular (IM) injection to all adults aged 18 through 55 years of age, with an indication for MCV4, and who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications to MCV4, which include: serious allergic reaction to a vaccine component or history of a serious allergic reaction to a prior dose. If the person has a history of Guillain-Barré Syndrome, they should consult with their physician before receiving vaccine. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.

- i. Indications for MCV4 include:
 - HIV–infected men who have sex with men
 - Men who have sex with men, regardless of HIV status who regularly have close or intimate contact with other men met either through an online website, smartphone application, a bar or a party.
 - Persons with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H).
 - Persons with anatomic or functional asplenia.
 - People routinely exposed to isolates of *N.meningitidis* in occupational settings (e.g., microbiologists).
 - First year college students living in residence halls, who have not received vaccination against meningococcal disease since their 16th birthday.
- ii. Persons who may require a second dose of MCV4 as part of their primary series include:

- Persons with persistent complement component deficiencies, functional or anatomic asplenia should receive a second dose of MCV 4 administered 8-12 weeks after the first dose.
 - Persons with HIV infection at increased risk for meningococcal disease should receive a second dose of vaccine 8-12 weeks after the first dose.
- iii. Boosters
- Persons with persistent complement component deficiencies or functional or anatomic asplenia are recommended to receive a booster dose every 5 years.
 - Microbiologists routinely exposed to isolates of *N.meningitidis* are recommended to receive a booster dose every 5 years if exposure is ongoing.
- iv. Persons recommended for vaccination with meningococcal polysaccharide vaccine, may receive meningococcal conjugate vaccine if the polysaccharide vaccine is unavailable.

2. Administer meningococcal polysaccharide vaccine (MPSV4) 0.5 ml subcutaneous (SC) injection to all adults aged 56 years of age and older with an indication for MPSV4, or persons 18-55 years with a contraindication to MCV4 but not MPSV4, and who have provided consent and do not fail the assessment, per the incorporated protocol. Persons will be screened for contraindications to MPSV4, which include: serious allergic reaction to a vaccine component or history of a serious allergic reaction to a prior dose. If the person has a moderate or serious illness, then vaccination should be deferred until the person is well. The person should be vaccinated if they have a minor illness such as diarrhea or respiratory tract illness (including otitis media) with or without a fever or on current antimicrobial therapy.

- i. Indications for MPSV4 include:
- HIV – infected men who have sex with men
 - Men who have sex with men, regardless of HIV status who regularly have close or intimate contact with other men met either through an online website, smartphone application, a bar or a party.
 - Persons with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H).
 - Persons with anatomic or functional asplenia.
 - People routinely exposed to isolates of *N.meningitidis* in occupational settings (e.g., microbiologists).
 - First year college students living in residence halls, who have not received vaccination against meningococcal disease since their 16th birthday.

D. Anaphylactic Treatment Agents

1. Administer Epinephrine as adult Epi-pen 0.3 mg IM (or epinephrine [USP 1:1000] administered 0.3 mL IM) if person being vaccinated exhibits symptoms of a severe allergic reaction or anaphylactic reaction: hives, itching, difficulty breathing, nausea, abdominal pain, change in mental status, drop in blood pressure. An adult dose Epi-pen or epinephrine with the necessary needles and syringes should be available where the vaccine is actually being administered. Call 911. One adult dose of EPI-pen IM (or epinephrine [USP 1:1000] administered 0.3 mL IM) may be repeated every 10-20 minutes up to 3 doses, if symptoms persist or worsen.

The certified pharmacists are limited to administering immunizations only in the course of such employment or pursuant to such contract with (name of entity); _____.
and this policy and procedure shall remain in effect from the effective date of this Standing Order _____ until rescinded or until _____ [end date]

Name of issuing physician or nurse practitioner: _____

Signature: _____ Date: _____

Title: _____

Institution/facility: _____

NYS License #: _____

NPI #: _____

