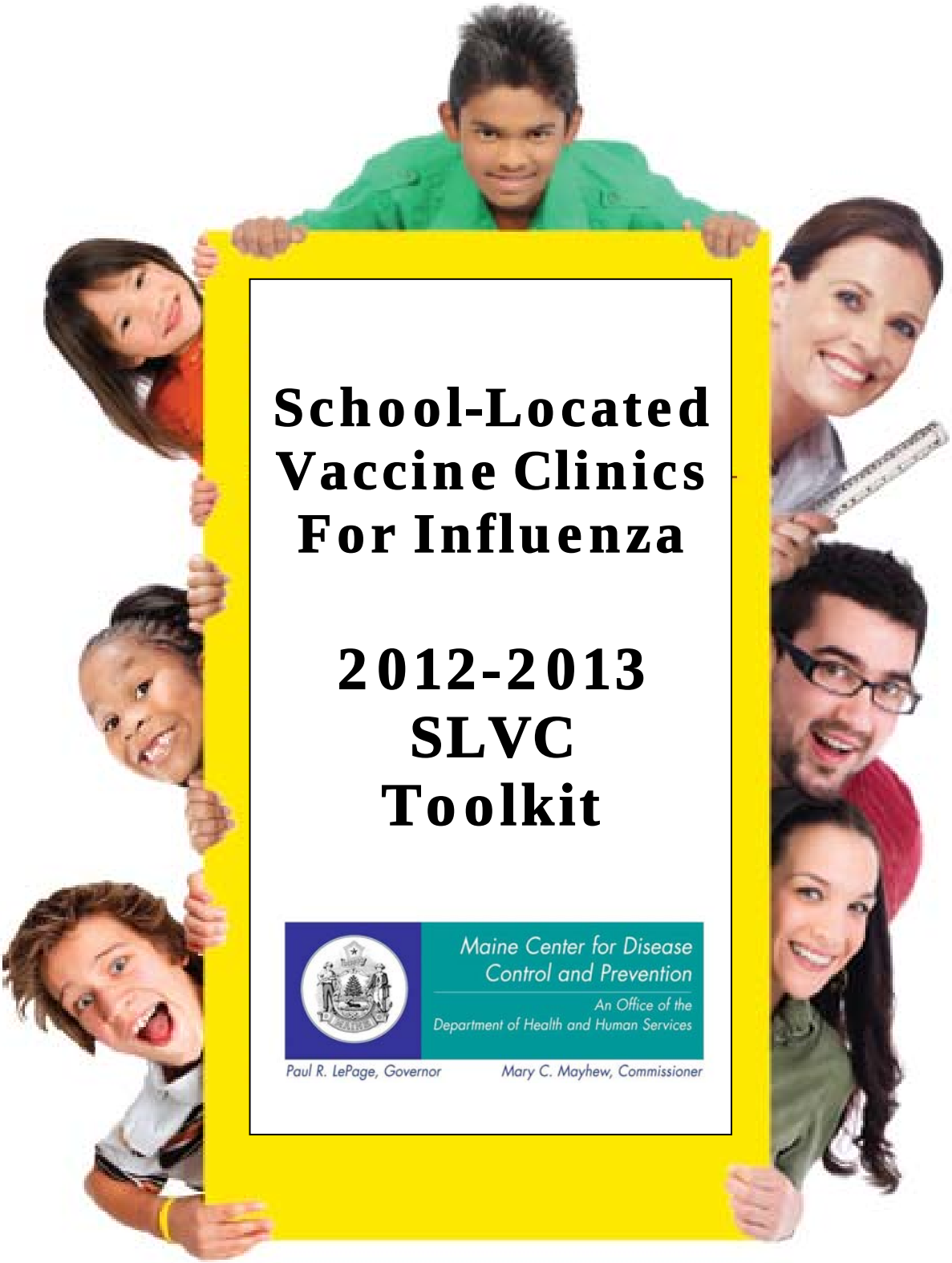

School-Located Vaccine Clinics For Influenza

2012-2013 SLVC Toolkit

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services

Paul R. LePage, Governor
Mary C. Mayhew, Commissioner

School-Located Vaccine Clinics for Influenza
2012-2013 SLVC TOOLKIT

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School-Located Vaccine Clinics for Influenza
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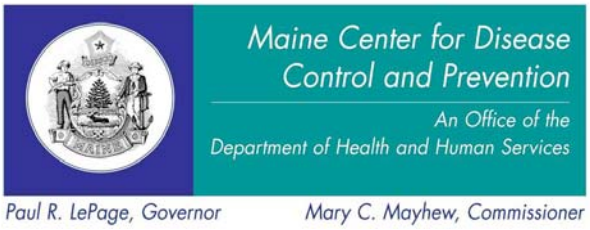
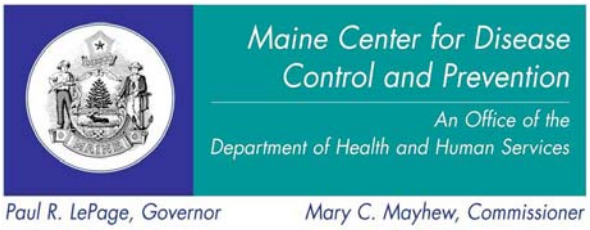


Eligibility for State-Supplied Influenza Vaccine in the School-Located Vaccine Clinic Setting

2012-2013 Influenza Season

Vaccine is supplied free of charge in the School-Located Vaccine Clinic (SLVC) setting to residents of the State of Maine that meet the following criteria:

- All Maine children enrolled in approved public and private schools
- Employees and volunteers of schools that provide SLVCs that are registered in ImmPact
- Pregnant women and their partners (includes students and staff)
- All individuals served by Maine's Tribal Health Centers
- All individuals served by Maine's municipal health departments (Portland and Bangor)



Webinar Notes: SLVC Registration -First steps

Preparing ImmPact to Register SLVCs

http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/webinars.shtml

To participate as a stakeholder/partner in a school-located vaccine clinic (SLVC) you need to establish the four roles listed below. These four roles translate to four sections (A-D) of the new electronic mass immunization registration process in ImmPact. Also included are the conditions required to fulfill these roles.

1. Section A: Clinic Authority

- Your Superintendent will sign as your clinic authority.
- Your site must be a school or school based health center (SBHC).
- You must have at least one ImmPact user.

2. Section B: Vaccine Provider

- Your site must have a Maine Immunization vaccine provider with a 4 digit pin and current year approved provider agreement.
- Review the Provider Agreement webinar if you need additional assistance with the provider agreement.

3. Section C: Vaccinator

- Your site must exist in ImmPact
- Contact the Maine Immunization program to set up a site if yours does not exist.
- You must have at least one ImmPact user.
- You may need to add your mass-immunization clinicians to the site.

4. Section D: ImmPact User Administrator

- For SLVC, your site must be the school or SBHC from Section A.

Other Information to Note:

1. Schools or SBHCs with a 4 digit pin and current approved provider agreement may participate as any or all of the roles in Sections A through D.
2. The school or SBHC that confirms as Section A must also confirm as Section D.
3. Sections B and C may be the same site or may be different (see Webinars for SLVC Registration, Scenarios 1 and 2).

In summary, there may be from 1 to 3 partners participating in the SLVC registration.

- At least one partner must be a school or SBHC.
- At least one partner must be a Maine Immunization vaccine provider with a 4 digit pin and current year approved provider agreement.

Note: You must complete one SLVC Registration MOA for each combination of partners that you will be using in your school district. *See SLVC Registration – Scenario 2 Webinar.*

Preparing your user to begin the registration process:

1. If your site does not have an active ImmPact user, print a user agreement from http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/forms-updates.shtml.
2. Fill out, sign, have your site's ImmPact administrator sign (if other than you), fax to the number on the form and phone the ImmPact helpdesk.
3. If your site has an active user who does not have access to Manage Sites (and Manage Clinicians for Section C), please ask your site's ImmPact administrator (if other than you) to contact the ImmPact helpdesk to change your ImmPact role.

Preparing your site to begin the registration process:

A. Site Contacts/Addresses

- In ImmPact, locate Manage locations/ Manage Sites in the blue menu panel to the left.
- Click Manage Sites.
- Click on the hyperlink for your site name.
- Scroll down to the Manage Site Contacts Section.
- For each role that your site will fulfill in the SLVC (Sections A through D above) you will be designating a contact.
    1. Locate and open the Address Type dropdown menu.
        - It will default to the Primary contact from the Address Type dropdown menu.

2. If the person whose name prefills is correct, fill in the required fields (in blue) and click save.
3. Note: If a different person will be the contact, click New Person.
    - Type in the first 3 letters of the last and first name and click find.
    - If the person is in the system their name will appear above the search field for you to select.
    - If the person is not found, fill out all required fields as their Primary address and click Associate, click Save.
    - You should now see the Section contact and address listed at the bottom of the page.
4. **Repeat Steps 1-3 for designating contacts for each Role in Sections B,C, and D that are not fulfilled by the School**.

B. **Adding Clinician Vaccinators: (Section C sites)** –

Note: You may wait to complete "associating" your clinician vaccinators with your SLVC site until after the registration process is started, however, it must be completed prior to the clinic event.

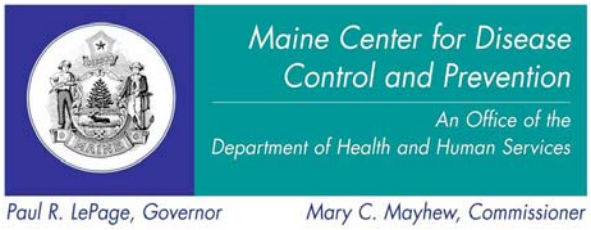
- In ImmPact, locate Manage Operations/ Manage Clinicians in the blue menu panel to the left.
- Click Manage Clinicians.
- Click Find.
- If there are clinicians associated to your site the Search Results will show you: you will see a list of hyper-linked names, the Site(s) they are associated to, their Vaccine Administrator Type and whether they are Active in ImmPact.
- If the clinician you want is listed and active, open the Vaccine Administrator Type dropdown menu,
    - select whether they are vaccinating only in the SLVC setting (mass-imm only), or vaccinating at other sites as well (site and mass-imm).
- If the clinician you want is not listed refer to the Manage Clinicians webinar to add your Vaccinator partner to ImmPact. In order to bill MaineCare this vaccinator must have an NPI Type 2 Number Registered with Maine Integrated Health Management System

You have now:

- *Learned what is required to participate as a Section partner*
- *Prepared your ImmPact user to begin the registration process*
- *Prepared your site to begin the registration process*

You need to:

- *Determine who will be fulfilling the roles in Sections A through D*
- *Complete Sections A through D of the registration*
- *View the next 3 Registration webinars.*
    - *SLVC Registration - Scenario 1: School Responsible for all SLVC Roles*
    - *SLVC Registration - Scenario 2:Multiple Partners for SLVC Roles*
    - *SLVC Registration - Final Steps*



Webinar Notes: SLVC REGISTRATION – Scenario 1*

School Responsible for all SLVC roles

http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/webinars.shtml

* Instructions in both Scenarios 1 and 2 require that the preparatory work to manage sites in ImmPact is completed. Refer to the webinar and written instructions for School Located Vaccine Clinic (SLVC) Registration First Steps

PART 1

These instructions are for completing page 1 Part 1 of the SLVC registration for a SLVC where only one site, the school district, will be participating and fulfilling all roles in Sections A through D.

- Log into you school or school based health center (SBHC) site.
- Locate Mass Immunization/Manage Registrations in the blue menu panel to the left.
- Click Manage Registration.
    - View the page to see if your site has any registrations pending.
    - If there is a registration in the block labeled Pending Action By Stakeholder, click edit to view the registration.
    - If there are no pending registrations, click New Registration.
- Page 1 of the registration consists of four sections. Each will be prefilled with its corresponding site contact and address.

  In Section A: Clinic Authority –

  - Verify the contact information is correct
  - Click "Confirm as Clinic Authority"

In Section B: Vaccine Provider –

- Verify the contact information is correct
- Click “Confirm as Vaccine Provider”

In Section C: Vaccinator–

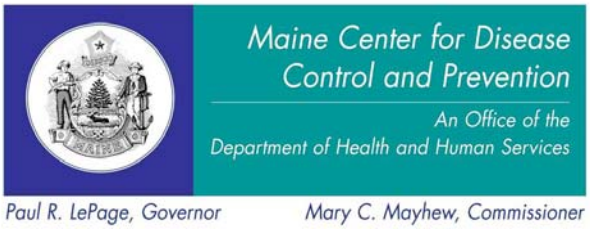
- Verify the contact information is correct
- Click “Confirm as Vaccinator”

In Section D: ImmPact User Administrator –

- Verify the contact information is correct
- Click “Confirm as ImmPact User Administrator”

- Once all sections have been confirmed, locate the NEXT button at the end of Section D.
- Click NEXT to continue on to page 2 of the registration.

Please view the Webinar and written instructions for **SLVC Registration – Final Steps**.



Webinar Notes: SLVC REGISTRATION – Scenario 2*

Multiple Partners for SLVC Roles

http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/webinars.shtml

* Instructions in both Scenarios 1 and 2 require that the preparatory work to manage sites in ImmPact is completed. Refer to the webinar and written instructions for School Located Vaccine Clinic (SLVC) Registration First Steps

PART 2

These instructions are for completing page 1 Part 2 of the SLVC registration for a SLVC where multiple sites will be participating and fulfilling all roles in Sections A through D.

For this example, one school site will fulfill the roles is Section A and Section D; another partner (site) will complete Section B and Section C.

Follow these instructions to enroll your partners who are performing the roles specified in Sections B and C.

- Log into you school or school based health center (SBHC) site.
- Locate Mass Immunization/Manage Registrations in the blue menu panel to the left.
- Click Manage Registration.
    - Click Search.
    - View the page to see if your site has any registrations pending.
    - If there is a registration in the block labeled Mass Immunization Registrations Pending Action By Stakeholder, click edit to view the registration.
    - If there are no pending registrations, click New Registration.

Page 1 of the registration consists of four sections. Each section - for which the corresponding site contact and address have been saved - will pre-fill.

For the Mass Immunization Clinic Type, select SLVC

- Click "Confirm Mass Immunization Clinic Type"

  In Section A: Clinic Authority –

  - Verify the contact information is correct
  - Click "Confirm as Clinic Authority"

  In Section D: ImmPact User Administrator –

  - Verify the contact information is correct
  - Click "Confirm as Clinic ImmPact User Administrator"

In Section B: Vaccine Provider –

- In the Transfer dropdown menu, locate the site who will be the Vaccine Provider.
- Click Transfer
  - You will be re-directed to the Manage Registration page.
  - The registration you transferred will be posted in the block labeled "Mass Immunization Registrations Pending Action By Partner".
  - ***You must notify the site that you have transferred a registration to them and instruct them to log into ImmPact.***
    - The Vaccine Provider site will log into ImmPact.
      - Locate Mass Immunization/ Manage Registration.
      - Click Manage Registration.
      - Click Search
      - Locate the registration in the block labeled "Mass Immunization Registrations Pending Action By Stakeholder"
      - Click Edit

In Section B: Vaccine Provider –

- Verify the contact information is correct
- Click "Confirm as Vaccine Provider"

In Section C: Vaccinator –

- Verify the contact information is correct
- Click "Confirm as Vaccinator"

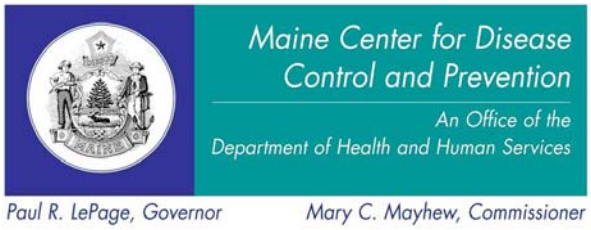
You will be re-directed to the Manage Registration page

- A message will be posted at the top of the page stating the registration has been transferred to the Clinic Authority for submission.
- The registration you transferred will be posted in the block labeled "Mass Immunization Registrations Pending Action By Partner".
- You should notify the site that you have transferred a registration to them.

Log into the school or school based health center (SBHC) site

- Locate Mass Immunization/Manage Registrations in the blue menu panel to the left.
- Click Manage Registration.
- Locate the registration in the block labeled "Mass Immunization Registrations Pending Action By Stakeholder"
- Click Edit
- Verify all sections have been completed.
- Click NEXT at the bottom of Section D to continue on to Page 2 of the SLVC registration.

Please view the Webinar and written instructions for **SLVC Registration – Final Steps.**



Webinar Notes: SLVC REGISTRATION – Final Steps

Mass Immunization: Memorandum of Agreement

http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/webinars.shtml

Please read the Memorandum of Agreement paragraph at the top of the ImmPact page.

Section 1. Mass Immunization Clinic Authority and Partner Relationship

Please indicate if the Mass Immunization Clinic Authority will be responsible for all roles or if a combination of partners will be fulfilling the roles required by this MOA.

1. Our Clinic Authority will be responsible for ***ALL*** of the roles listed in the electronic portion of this MOA.
    a. If you select YES, the Clinic Authority column will fill "Responsible" for all line items in section 2
    b. If you Select NO, you must select yes for number 2
2. Our Clinic Authority will be working with outside stakeholders to assist in performing Mass Immunization Clinic(s) / Events
    a. If you select Yes, continue to section 2 and designate who is responsible for each line item. You may also designate who is participating.

NOTE: If you click YES for number 1 but meant NO, change item 1 to NO and select YES for number 2. This will clear the selections from the Clinic Authority column.

Section 2: Mass Immunization Roles

Please indicate the agreed upon responsible party and/or participants for each of the roles below.

- Each row must have one "Responsible" selected.
- Each row may have multiple "Participating" selections.

When you have completed Section 1 and Section 2 of the MOA, click NEXT to move forward to the signature page.

- Verify that the information on the signature page is correct.
- Click the button labeled "Submit Agreement Form" to send the MOA to the state for approval.
- You will be returned to the Manage Registration page.
- Your submitted registration agreement will be posted in the block labeled "Mass Immunization Registrations Pending Action By State"
- Click on the Print Sig link.
- Print the document.
- Have each partner sign and date the form.
- Fax the form to 207-287-8127*.

Please note that the Maine CDC will not move forward in approving your MOA until the signature page is received by ImmPact.

School-Located Vaccine Clinics for Influenza

2012-2013 SLVC TOOLKIT

Part 2: DOCUMENTS TO SEND HOME

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2.3 Live Intranasal Influenza Vaccine VIS
2.4 Inactivated Influenza Vaccine VIS
2.5 Health Screen and Permission Form
2.6 Information Sheet for Parents of Children Less than 9 yrs Old

(SCHOOL HEADER)

_____ School will be having an influenza vaccination clinic during the month of _____.

Please read the Vaccine Information Sheets attached to this letter and complete the attached Health Screen & Permission Form and return to the school by _____.

- ✓ You will be notified if there is change in the planned dates of school flu clinics.
- ✓ **Reminder**: Some children less than 9 years of age may need 2 doses of flu vaccine this year.
- ✓ Please see the Information Sheet for Parents to determine if your child will need 2 doses.
- ✓ Please see the School-Located Vaccine Clinic Fact Sheet for Parents about the advantages to having your child vaccinated in the school-located vaccine clinic setting.

For information about flu and the vaccine go to www.maineflu.gov, www.flu.gov, or http://www.cdc.gov/flu

For questions about the flu vaccine, call Maine Center for Disease Control & Prevention (Maine CDC) at 1-888-257-0990, Monday – Friday 9 a.m. – 5 p.m.

For questions about the vaccine clinics at our school, please call the school nurse at _____.

OPTIONAL: *Parents are encouraged but not required to attend these clinics with their child.*

Sincerely,

Please be sure to complete and return the Health Screen & Permission form!

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services

Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Fact Sheet: School-Located Vaccine Clinics for Flu

Q. What is influenza (flu)?

A. The flu is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death.

The best way to prevent the flu is by getting a flu vaccination each year.

Some people, such as older people, young children, and people with certain health conditions (such as asthma, diabetes, or heart disease), are at high risk for serious flu complications.

Q. How does the flu spread?

A. Flu viruses spread mainly from person to person through coughing or sneezing. Sometimes people may become infected by touching something with flu viruses on it and then touching their mouth or nose.

Q. What can I do to prevent my child from getting the flu?

A. Maine CDC recommends a yearly flu vaccine as the first and most important step in protecting against this serious disease. While there are many different flu viruses, the flu vaccine protects against the three main flu strains that research indicates will cause the most illness during the flu season. The vaccine can protect you from getting sick from these three viruses or it can make your illness milder if you get a different flu virus. In addition, everyday preventive steps like frequent hand washing can decrease your child's chances of getting the flu.

Q. Why are children getting vaccinated at school?

A. School clinics provide an opportunity for more children to be vaccinated, which makes for a safer and healthier school environment. While adults usually have many places to get flu vaccine (work, pharmacy, community clinics, etc) there are fewer opportunities for children outside of their healthcare providers' office. Children who receive flu vaccine are much less likely to get the flu and miss school.

Q. What are the advantages of having my child vaccinated at a school-based clinic?

- **The vaccine is free:** There is no fee for the vaccine and no fee or copayment for an office visit. The clinic provider will ask for your insurance information on your permission form in order to bill your insurance carrier for administering the vaccine. **No child will be denied the opportunity to be vaccinated and there will be no costs passed on to the families.**
- **Parents do not need to miss work:** If your child is vaccinated at the school-based clinic you may or may not need to be present. Consent forms are provided to parents ahead of time. Please check with your school to see if parent attendance is required.
- **Students do not need to miss school**: If your child is vaccinated in the school-based clinic, he or she will not need to be taken out of school for an appointment with your health care provider.
- **Vaccine administration information will be available to your usual health care provider:** Information on this vaccination will be entered into the State's Immunization Registry and this information is available to your health care provider.

VACCINE INFORMATION STATEMENT

Influenza Vaccine
Live, Intranasal
What You Need to Know

2012 - 2013

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:

1. **Live, attenuated** influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.

2. **Inactivated** (killed) influenza vaccine, the "flu shot," is given by injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts about a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people **2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below).

4 Some people should not receive LAIV

LAIV is not recommended for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- **Adults 50 years of age and older or children from 6 through 23 months of age**. (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women.
- People who have long-term health problems with:
  - heart disease
  - lung disease
  - asthma
  - kidney or liver disease
  - metabolic disease, such as diabetes
  - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). *Close contacts of other people with a weakened immune system (such as those with HIV)* ***may*** *receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.*
- Children or adolescents on long-term aspirin treatment.

Tell your doctor if you have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.

Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.

Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your doctor will help you decide whether the vaccine is recommended for you.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Tell your doctor if you have gotten any other vaccines in the past 4 weeks.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I receive influenza vaccine?

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:
Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and
www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

9 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

Influenza Vaccine
Inactivated
What You Need to Know

2012 - 2013

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, the "flu shot," is given by injection with a needle.

2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A "high-dose" inactivated influenza vaccine is available for people 65 years of age and older. Ask your doctor for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your doctor for more information.

3 Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

WHEN

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

4 Some people should not get inactivated influenza vaccine or should wait.

- Tell your doctor if you have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

- Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.
- Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your doctor will help you decide whether the vaccine is recommended for you.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:
• soreness, redness, or swelling where the shot was given
• hoarseness; sore, red or itchy eyes; cough
• fever • aches • headache • itching • fatigue
If these problems occur, they usually begin soon after the shot and last 1-2 days.

Moderate problems:
Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time appear to be at increased risk for seizures caused by fever. Ask your doctor for more information.

Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Severe problems:
- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and **www.cdc.gov/vaccinesafety/Activities/Activities_Index.html**

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Your doctor can give you more information.

6 What if there is a severe reaction?

What should I look for?
- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

8 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

HEALTH SCREEN & PERMISSION FORM – Influenza Vaccine 2012-2013

School: _____

Full Name:	Date of Birth: / /	Age:	Gender: ☐ M ☐ F
Street Address:	Town/City:	Zip Code:	Daytime Phone:
Grade:	Teacher:	School Administrative Unit (District)	

Please answer the following questions about <u>the person named above</u>. Comments may be written on the back of this form.

	YES	NO
1) Does this person have a severe allergy to eggs, gentamicin, gelatin, or arginine?		
2) Has this person ever had a severe reaction to an influenza immunization in the past?		
3) Has this person ever had Guillain-Barre Syndrome?		
If you answered "yes" to any questions 1-3, please see your healthcare provider for flu vaccination		
4) Does this person have asthma, diabetes, lung disease, heart disease, kidney problems, a blood disorder, muscle or nerve disorders that affect breathing or swallowing such as a seizure disorder or Cerebral Palsy or on long-term aspirin treatment?		
5) Has this person received any other vaccinations in the past 4 weeks? If YES: Type_____ Date: _____		
6) Does this person have a weakened immune system, or come in close contact with someone who has a severely weakened immune system?		
7) Is this person pregnant or could this person be pregnant?		
If you answered "yes" to any questions 4-7, this person cannot receive the intranasal flu vaccine		
8) Is this person insured by MaineCare (Medicaid)? MaineCare ID #:_____		
9) Is this person an American Indian or an Alaskan Native?		
10) Is this person under-insured (has insurance that does not cover flu vaccine)?		
11) Is this person uninsured?		

12) Health Care Provider Name:_____ Phone Number:_____

13) Health Insurance: Name of Company: _____
ID Number: _____ Group number: _____

PERMISSION TO VACCINATE

- ✍ I was given a copy of the 2012-2013 Influenza Vaccine Information Statements, I have read them or had them explained to me and I understand the benefits and risks of the Influenza vaccine.
- ✍ I give permission for a record of this vaccination to be entered into the ImmPact Registry and to be used to bill either MaineCare or private insurance for the cost of providing the vaccine
- ✍ I am giving my consent for this person to receive the most appropriate vaccine, as determined by the health care provider giving the vaccination.
- ✍ If my child refuses to receive the injection and does not have asthma, you have my permission to give the nasal flu mist.
- ✍ **I give permission for the flu vaccine to be given to the person named above by signing below.**

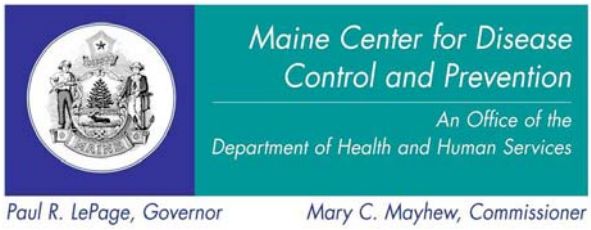
X_____ Date:_____

Signature of parent/guardian if person to be vaccinated is a minor or Signature of adult to be vaccinated

Printed Name of Parent or Guardian**:**_____

FOR OFFICE USE ONLY:

Date Dose Administered	Vaccine Manufacturer	Lot Number	Dose Volume	Signature and Title of Vaccinator	Body Site	Route	VIS date
/ /						□ IM □ Intranasal	07/2/12



Information Sheet for Parents:
Determining the Number of Seasonal Influenza Vaccinations for Children Younger Than 9 Years Old

If your child is younger than 9 years old, the number of seasonal flu vaccines your child needs in order to be protected from the flu in the 2012-2013 season depends on your child's previous vaccination history.

Please answer the following question to find out if your child needs one (1) or two (2) doses of 2012-2013Seasonal Influenza Vaccine:

1. Did this child receive ever receive influenza vaccine?

☐ NO or NOT SURE ►Child should receive **2 doses** this season administered a minimum of four weeks apart

☐ YES ►Go to Question 2

2. Did this child receive a total of 2 or more doses of seasonal influenza vaccine since July 1, 2010?

☐ NO or NOT SURE ►Child should receive **2 doses** this season administered a minimum of four weeks apart

☐ YES ►Child should receive **1 dose** this season

Note: If your child needs two doses of vaccine, check with your school about second doses or with your child's health care provider.

School-Located Vaccine Clinics for Influenza

2012-2013 SLVC TOOLKIT

Part 3: CLINIC GUIDANCE

Table of Contents

3.1 Framework for Planning SLVCs for Influenza
3.2 Clinic Supply Ordering Guidelines – Letter from McKesson
3.3 Model Plan for Implementing SLVCs for Influenza
3.4 Health Screen and Permission Form
3.5 Health Screen and Permission Form Guidance
3.6 Advisory Committee on Immunization Practices (ACIP): 2012-2013 Influenza Vaccine Recommendations
3.7 DOE SLVC Template – Adult Refusal to Stay After Receiving Vaccine
3.8 Model Plan: Reporting Adverse Events Following Influenza Vaccination

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services

Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Framework for Planning School-Located Vaccine Clinics (SLVCs) for Influenza

These recommendations and guidelines were developed to assist with planning school-located vaccination clinics (SLVC) for influenza.

This document provides general guidance to help ensure smooth operations at SLVCs and is broken into 4 phases, each with specific considerations:

1. Planning
2. Clinic Set-up
3. Clinic Operations
4. After-Clinic Activities

PHASE 1: Planning

- Identify SLVC leaders for overall vaccination delivery operations.
- Identify partners that will be fulfilling mass immunization roles in ImmPact
- Register your clinics according to guidelines found in the SLVC Toolkit
- Develop a communication plan among all clinic partners.
- Identify clinic process, including: location, size, # of stations, and staff required.
- Identify staff to fill the positions.
- Meet the language needs of the community using multi-lingual staff as appropriate.
- Prepare staff members regarding their roles and responsibilities during clinic operations.
- Cross-train staff members, if possible, to enable flexibility in meeting needs at various stations as demands fluctuate.
- If possible, provide additional staff to meet fluctuating clinic demands and schedule breaks for staff.
- Establish restraint policies and responsibilities.
- Ensure the presence of an onsite emergency medical kit and supplies.
- Ensure that emergency procedures are in place to respond to urgent medical problems.

Vaccine Clinic Location

- If you plan to vaccinate a large number of students at one time, it is recommended clinic planners consider holding the clinic in school gyms, auditoriums, or other large covered spaces that can accommodate a large number of students and staff.
- If you plan to vaccinate smaller numbers of students in small groups by classroom, it is recommended that you carefully consider the building layout to ensure adequate clinic flow. Items such as adequate lighting and heating, functional and accessible restrooms, adequate space for all clinic functions such as screening, registration, vaccine storage, vaccination, and staff breaks are considered.

Clinic Notification & Parental Consent

- Ensure that adequate vaccine is available for the clinic.
- Best practices indicate making consent forms and information packets available to parent 7-61 days prior to the clinic date and sent reminders to parents to return the consent forms. Reminders can include mailings to parents and making personal or automated phone calls.
- Prior to vaccinating students, staff should review the consent forms to verify that parents have fully completed the forms.
- Consent forms are available in the current season's SLVC Toolkit

PHASE 2: Clinic Set-up

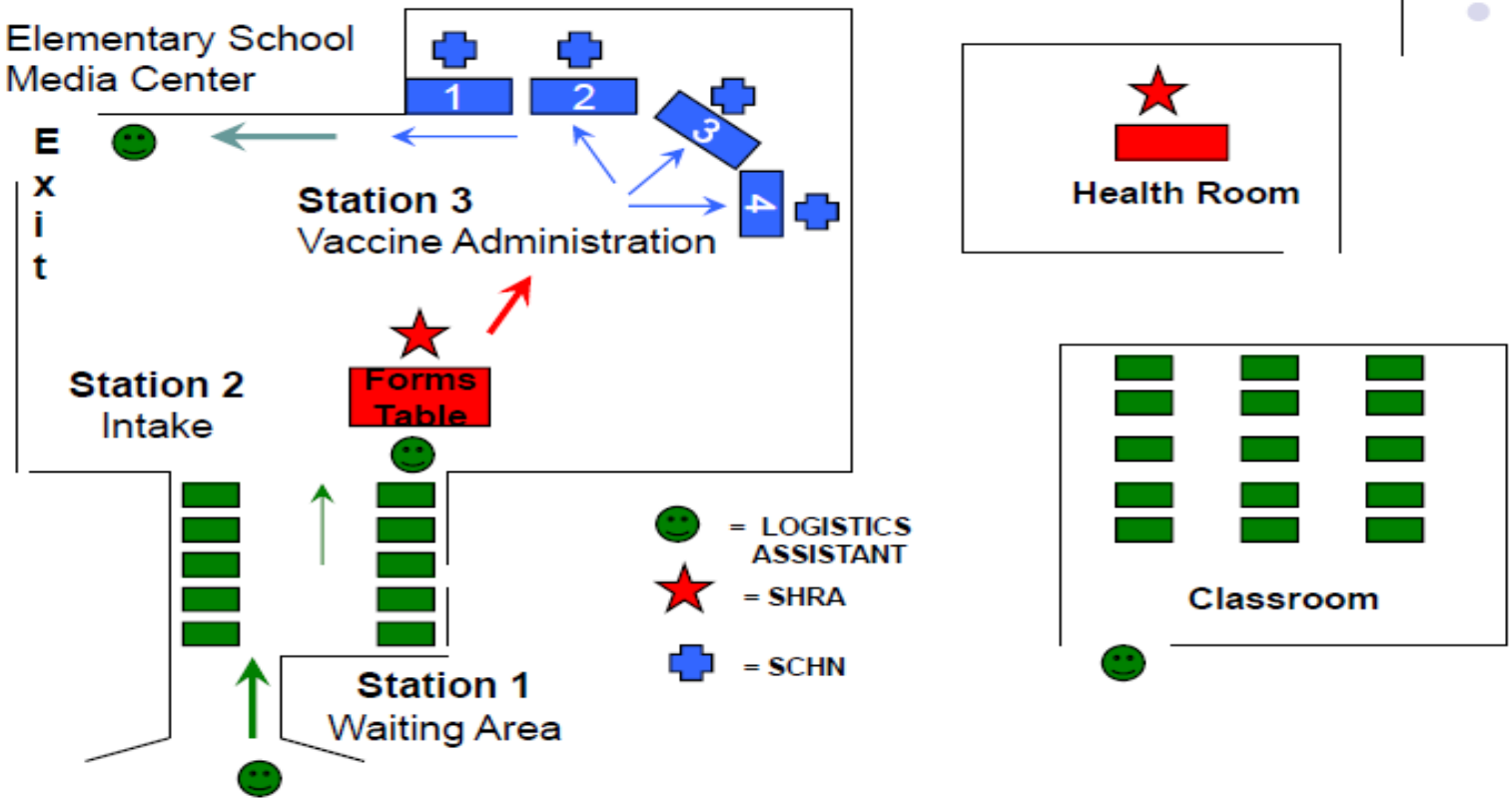
Clinic Lay-Out and Specifications

- See "Example of Influenza Vaccine Clinic Lay-Out" on page 4.
- You may want to adjust your clinic's lay-out based on items identified during the initial clinic planning phase.
- An inventory of suggested supplies can be found at the end of this document
- Use signs in multiple languages, as needed.
- Provide seating for students and staff if possible.
- Provide a waiting area where students can be observed after vaccination.

Clinic Security/Safety

- If your school will be utilizing outside volunteers to help operate your clinic, it is recommended that you consider using name tags or id badges to ensure those inside the clinic are authorized to be there.
- Assure that vaccine is stored in a safe and secure location that can be locked and access can be restricted to medical personnel only.
- Recruit local volunteers as needed to assist with clinic flow.
- Depending on the time of the clinic (during school or off-hours) you may want to coordinate and collaborate with local community resources.

DIAGRAM OF ADMINISTRATION PLAN
School Size 450 – 600 students



PHASE 3: Clinic Operations

- Accommodations for special-needs students will need to be taken into account (e.g., persons with disabilities) for expedited access into the clinic.
- Direct arriving students into clinic to expedite vaccine delivery.
- Ensure all students receiving vaccine have completed all forms, including the consent form and health screen.
- Based on the results on the health screening process, determine the correct vaccine presentation (Multi-dose, pre-filled, nasal mist, etc) for each student and direct them to the correct vaccination station.
- In order to keep the flow moving it is recommended that non-medical clinic staff be utilized as supply runners to assist in the clinic supply management process.
- Maintain a steady flow of students through the clinic so that vaccinators are never without a client at their stations; redirect students to other stations if bottlenecks occur.

PHASE 4: After-Clinic Activities

- After-clinic activities need to be part of the initial planning process.
- Step 1: Close the vaccine clinic
    - Clear all students from the vaccination area prior to closing
    - Post clear signage that the indicating that the site is closed
    - Assign staff for breakdown of site
    - Catalog and repair consumable supplies
    - Collect and dispose of trash
    - Bag and properly dispose of medical waste (sharps containers)
- Step 2: Clean-up
    - Follow your schools policy regarding post-event clean-up
- Step 3: Reporting doses administered
    - At the conclusion of the vaccine clinic, report clinic information to Clinic Authority and to Maine CDC, as required by the Maine Immunization Program.
    - Doses administered must be entered into ImmPact as soon as possible after the completion of SLVC.
        - Delays in doses administered reporting can have multiple effects
            - Results in delayed billing and reimbursement for vaccine
            - Inability of the person's healthcare provider to view up-to-date vaccination history, which may lead to double vaccination of the patient.

Suggested Supply List

Clinical Supplies:

Small Non latex Exam Gloves	100/Box	2	
Medium Non latex Exam Gloves	100/Box	4	
Large Non latex Exam Gloves	100/Box	2	
XL Non latex Exam Gloves	100/Box	1	
Gauze pads	2" by 2"; tray of 50	2	
Biohazard Bags	Red	1	
Bandages	3/4" by 3"; pack of 100	4	
Under pads	17.5" by 24"; pack of 100	1	
Alcohol wipes	Box of 200	2	
Disinfecting wipes	25 sheets per container	2	
Sanitizer Gel	8 oz; 12 per case	1	
Sharps containers	1 gallon, red	4	

Administrative Supplies:

Tote Bin	50 Gallon; L 39.5" W 24.5" H 21"	1	
Hanging File Organizer	Sheet capacity 100	1	
Calculator	Pocket	5	
Re-sealable Bags	50 per box	1	
Envelopes	PK100	1	
Highlighters	5PK; Assorted	1	
Assorted Color Permanent Markers	3PK	1	
Blue Pens	12 per pack	5	
Black Pens	12 per pack	2	
Red Pens	12 per pack	2	
Pencil/Pen Case	6 compartments	2	
Paper Pad	12 per pack	1	
Stapler		2	
Staple Remover	3PK	1	
Standard Staples	5,000 per pack	1	
Tape		3	
Office Scissors		2	
Rubber Bands		1	
Push Pins – Assorted Colors	100 per box	1	
White Out	3PK	1	
Index Cards	50 per pack	6	
Paper Clips	100 per pack	2	
Sticky Notes	12/pack	1	
Ruler	each	2	
Printer Paper	ream	2	
Tape Dispenser	each	2	

McKESSON
Empowering Healthcare

August 28, 2012

Dear School Vaccine Clinic Coordinator,

This notice is being sent to all schools that are considering participation in school-located vaccine clinics (SLVC) this fall.

McKesson is pleased to announce that Maine CDC will again be offering an arrangement to allow school districts that have registered their school-located vaccine clinics to purchase supplies at no cost to the school district. You will have access to a pre-set list of supplies that may be needed for school vaccine clinics. If you already have all the supplies you need for your clinic, there are also supplies available on this list that may help in the prevention and control of influenza in your school.

How it works:

User Names from last year have been reset, however new passwords will be needed. Remember, before purchasing supplies your SLVC site registration must be approved by Maine CDC. Please contact Jennifer Rancourt, McKesson Account Manager, at jennifer.rancourt@mckesson.com or at 207-332-4602 to reactivate last year's account or to activate a new account.

Once your account is activated, please follow these instructions to place an online order via our website at https://mms.mckesson.com

- Please go to the above web address and type in your username and password. You will click on the ship-to address. (If you do not see your correct ship-to address, email me at jennifer.rancourt@mckesson.com or call me at 207-332-4602.)
- Once you have confirmed the shipping address, you may order any supplies from the online catalog developed specifically for Maine's SLVCs. Maine CDC is currently working on the budget amounts and each district will be notified individually of their award, with a minimum of $500 worth of clinic supplies to each participating school district.
- Click on the "LIST" tab, "my lists", "flu" and all the products that you have access to are listed.

- **When you see a product you would like to add to your shopping basket put the quantity in the box and click on the green + sign. This will add it to your basket.**
- **Once you have put all items into your shopping basket. Click on Purchase.**
- **In the PO space, please put your school name and date**
- **Click "Continue to next step", click on "continue order" and you will receive an order number. A confirmation email will be sent to the user's email address.**
- **Items will be shipped directly to your designated ship-to address.**
- **Items that are stocked should arrive the next business day, if order placed by 12:00 noon. Drop-shipped items shipping will vary based on manufacturer.**

We look forward to working with you again this year. If you have ordering questions, Customer Service is available at 1-800-654-7240. Them Maine CDC SLVC account number is #80641.

Sincerely,

Jennifer Rancourt, McKesson Account Manager
on behalf of The Maine CDC SLVC Team

Model Plan for Implementation of School-Located Vaccine Clinics

The following plan provides guidelines to be followed at mass immunization clinics designated as School-Located Vaccine Clinics (SLVCs).

1. The Clinic Authority will work in coordination with the Vaccine Provider (the entity ordering vaccine supply and managing inventory) and the Vaccinator (the entity with licensed professionals that administer vaccine in the clinic setting shall be authorized to administer the vaccine at immunization clinics.

2. The Clinic Authority will use the consent form to obtain a relevant health history for the purpose of determining possible contraindications to receiving vaccine.

3. The Clinic Authority will have screener check for moderate or severe illness (including fever > 100) in clients. Persons who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If the client is ill, they should be directed to another SLVC for vaccination or to their healthcare provider. Persons with mild illness can usually get the vaccine.

4. An emergency plan must be in place in the event of anaphylaxis or symptoms of immediate hypersensitivity following administration of the vaccine.

- **Prior to the clinic, Vaccinators and other health professionals attending the clinic shall be familiar with the emergency procedures for anaphylaxis and the administration of Epinephrine and Benadryl**.

  Note: An emergency Kit Containing the following items must be at the clinic site:

  - 2 ampules Epinephrine (adrenaline) 1:1000
  - 1 vial of Benadryl (diphenhydramine) 50mg/ml
  - 4 TB syringes
  - (2) 3cc syringes (w/needle – 22-25 ga, 1–1.5” length)
  - Alcohol swabs
  - B/P cuff and stethoscope
  - CPR mask

  Ref: MMWR (June 29, 2001/Vol. 50/No. RR-11; 1:42)

- There must be a second responsible person present at each clinic site while vaccine is being administered in order to activate the Emergency Medical Services if necessary. The second person may be from a program other than the school.

5. There shall be no pre-filling of syringes at clinics. All doses of vaccine and emergency medication shall be drawn up at the time of administration.

6. During the clinic, if the vaccine is stored in a transport container/cooler, the insulating barrier must be left in place between the vaccine and the refrigerated/frozen packs.

7. During the clinic, the SLVC staff shall check the temperature in the cooler, as vaccine is accessed or at least hourly to ensure that the cold chain is not broken. If the temperature range is out of the acceptable CDC ranges for storage of vaccine (35° to 46°F) the following action must be taken immediately:

    a. Label the vaccine that it has been stored out of range

    b. Notify the SLVC Vaccine Provider

    c. Notify the manufacturer of the product for instructions in handling the vaccine (see contact numbers below).

    d. Notify the Maine Immunization Program (287-3746) if vaccine comes from the Maine Immunization Program.

8. The Vaccinator shall verify that the medical screening/permission form is complete and shall be used for the purpose of determining possible contraindications to receiving the vaccine.
    - As recommended best practice, copy of the Vaccine Administration Record (VAR) or consent form and the health history shall be retained for 3 years by the Vaccine Provider.

9. Persons with a negative health history (no contraindications) or who have written permission from their primary health care provider may receive the vaccine.

10. Each Vaccinator shall have their own sharps container at their station. During use, sharps containers shall be:

    a. Easily accessible to personnel and located at the area where sharps are used or can be found.
    b. Maintained upright throughout use.
    c. Replaced when ⅔ full.

11. The Vaccinator shall notify the client that they are expected to remain for 15 minutes at the clinic site after receiving the vaccine for the purpose of observing for a reaction to the vaccine. All minors shall be observed for 15 minutes. If an adult client refuses to stay for the 15-minute observation period the Vaccinator shall obtain their signature on the Adult Refusal to Stay After Receiving Vaccine statement.

12. If an adverse reaction should occur, the Vaccinator and clinical staff shall refer to "Medical Management of Vaccine Reactions in Children and Teens" available at www.immunize.org/catg.d/p3082a.pdf. and the Model Emergency Plans provided with this toolkit. An adult can be treated using the same protocol for the "13 years and older" dosing schedule.

State Supplied Influenza Vaccine Manufacturer Contact Information for 2012/2013 SLVCs

Manufacturer	Phone Number	Products
GlaxoSmithKline	866-475-8222	Fluarix and FluLaval
Medimunne	877-633-4411	Flumist
Sanofi- Pasteur	800-822-2463	Flu-zone including High Dose

HEALTH SCREEN & PERMISSION FORM – Influenza Vaccine 2012-2013

School: _____

Full Name:	Date of Birth: / /	Age:	Gender: ☐ M ☐ F
Street Address:	Town/City:	Zip Code:	Daytime Phone:
Grade:	Teacher:	School Administrative Unit (District)	

Please answer the following questions about <u>the person named above</u>. Comments may be written on the back of this form.

	YES	NO
1) Does this person have a severe allergy to eggs, gentamicin, gelatin, or arginine?		
2) Has this person ever had a severe reaction to an influenza immunization in the past?		
3) Has this person ever had Guillain-Barre Syndrome?		
If you answered "yes" to any questions 1-3, please see your healthcare provider for flu vaccination		
4) Does this person have asthma, diabetes, lung disease, heart disease, kidney problems, a blood disorder, muscle or nerve disorders that affect breathing or swallowing such as a seizure disorder or Cerebral Palsy or on long-term aspirin treatment?		
5) Has this person received any other vaccinations in the past 4 weeks? If YES: Type_____ Date: _____		
6) Does this person have a weakened immune system, or come in close contact with someone who has a severely weakened immune system?		
7) Is this person pregnant or could this person be pregnant?		
If you answered "yes" to any questions 4-7, this person cannot receive the intranasal flu vaccine		
8) Is this person insured by MaineCare (Medicaid)? MaineCare ID #:_____		
9) Is this person an American Indian or an Alaskan Native?		
10) Is this person under-insured (has insurance that does not cover flu vaccine)?		
11) Is this person uninsured?		

12) Health Care Provider Name:_____ Phone Number:_____

13) Health Insurance: Name of Company: _____
ID Number: _____ Group number: _____

PERMISSION TO VACCINATE

- ✍ I was given a copy of the 2012-2013 Influenza Vaccine Information Statements, I have read them or had them explained to me and I understand the benefits and risks of the Influenza vaccine.
- ✍ I give permission for a record of this vaccination to be entered into the ImmPact Registry and to be used to bill either MaineCare or private insurance for the cost of providing the vaccine
- ✍ I am giving my consent for this person to receive the most appropriate vaccine, as determined by the health care provider giving the vaccination.
- ✍ If my child refuses to receive the injection and does not have asthma, you have my permission to give the nasal flu mist.
- ✍ **I give permission for the flu vaccine to be given to the person named above by signing below.**

X_____ Date:_____

Signature of parent/guardian if person to be vaccinated is a minor or Signature of adult to be vaccinated

Printed Name of Parent or Guardian**:**_____

FOR OFFICE USE ONLY:

Date Dose Administered	Vaccine Manufacturer	Lot Number	Dose Volume	Signature and Title of Vaccinator	Body Site	Route	VIS date
/ /						☐ IM ☐ Intranasal	07/2/12

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

GUIDANCE DOCUMENT
HEALTH SCREEN & PERMISSION FORM – Influenza Vaccine

PURPOSE OF FORM

A. Screen both children and staff in the school clinics to make sure that they can receive the vaccine in the school clinic setting (Q1-4)
B. Select the appropriate type of vaccine to administer (Q5-8)
C. Obtain administrative information to be used for billing (Q9-14)
D. Obtain consent which includes permission to have information entered into ImmPact registry
E. Obtain signature from parent/guardian, or staff member for vaccination

A. QUESTIONS 1-4: WHO SHOULD BE REFERRED TO THEIR OWN HEALTH CARE PROVIDER?

Questions 1-4 determine if the student or staff can be vaccinated in the school located vaccine clinic setting. If any of the questions are answered with a YES then:

- This person cannot receive their 2012/2013 Influenza Vaccine in the school setting
- Refer staff or parent/guardian to see their health care provider

B. QUESTIONS 5-8: WHAT TYPE OF VACCINE SHOULD BE GIVEN?

Questions 5-8 help to determine which type of the 2012/2013 Influenza Vaccine is appropriate for each person based on their medical history. If any of these questions are answered with a YES then:

- This person can not receive the nasal spray formulation, also known as Live, Intranasal Flu Vaccine on the Vaccine Information Statement (VIS)
- This person must receive the vaccine by an injection also known as Inactivated Flu Vaccine on the VIS.

C. QUESTIONS 9-14: ADMINISTRATIVE INFORMATION

- Questions 9-14 provide information that will be used for administrative purposes.

D. CONSENT TO VACCINATE INCLUDING PERMISSION TO ENTER INFORMATION INTO ImmPact

E. SIGNATURE OF PARENT/GUARDIAN ADULT

Signature of the parent/guardian/staff indicates the consent of the parent/guardian/adult for the child or staff member to receive vaccine and to enter the information into the ImmPact immunization registry

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) — United States, 2012–13 Influenza Season

In 2010, the Advisory Committee on Immunization Practices (ACIP) first recommended annual influenza vaccination for all persons aged ≥6 months in the United States (*1*). Annual influenza vaccination of all persons aged ≥6 months continues to be recommended. This document 1) describes influenza vaccine virus strains included in the U.S. seasonal influenza vaccine for 2012–13; 2) provides guidance for the use of influenza vaccines during the 2012–13 season, including an updated vaccination schedule for children aged 6 months through 8 years and a description of available vaccine products and indications; 3) discusses febrile seizures associated with administration of influenza and 13-valent pneumococcal conjugate (PCV-13) vaccines; 4) provides vaccination recommendations for persons with a history of egg allergy; and 5) discusses the development of quadrivalent influenza vaccines for use in future influenza seasons. Information regarding issues related to influenza vaccination that are not addressed in this update is available in CDC's *Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010* and associated updates (*1,2*).

Methodology for the formulation of the ACIP annual vaccine recommendations has been described previously (*1*). The ACIP Influenza Work Group meets every 2–4 weeks throughout the year. Work Group membership includes several voting members of ACIP and representatives of ACIP Liaison Organizations. Meetings are held by teleconference and include discussion of influenza-related issues, such as influenza surveillance, vaccine effectiveness and safety, coverage in groups recommended for vaccination, program feasibility, cost-effectiveness, and anticipated vaccine supply. Presentations are requested from invited experts, and published and unpublished data are discussed. CDC's Influenza Division provides data on influenza surveillance, antiviral resistance, and vaccine effectiveness. CDC's Immunization Safety Office provides information on vaccine safety, and CDC's Immunization Services Division provides information on vaccine distribution and coverage.

> Recommendations for routine use of vaccines in children and adolescents are issued by CDC and are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics, the American Academy of Family Physicians (AAFP), and the American College of Obstetrics and Gynecology (ACOG). CDC recommendations for routine use of vaccines in adults are harmonized to the greatest extent possible with recommendations made by AAFP, ACOG, and the American College of Physicians. The Advisory Committee on Immunization Practices (ACIP) is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of CDC on use of vaccines in the civilian population of the United States. ACIP members are named by the Secretary of the U.S. Department of Health and Human Services. ACIP recommendations become CDC policy once approved by the Director of CDC, on the date published by *MMWR*.

Vaccine Strains for the 2012–13 Influenza Season

U.S. influenza vaccines for 2012–13 will contain A/California/7/2009 (H1N1)-like, A/Victoria/361/2011 (H3N2)-like, and B/Wisconsin/1/2010-like (Yamagata lineage) antigens. The influenza A(H3N2) and B antigens differ from the respective 2010–11 and 2011–12 seasonal vaccine antigens (*3*). The influenza A(H1N1) vaccine virus strain is derived from an influenza A(H1N1)pdm09 (2009[H1N1]) virus and was included in the 2009(H1N1) monovalent pandemic vaccine as well as the 2010–11 and 2011–12 seasonal vaccines.

Recommendations for Vaccination

Routine annual influenza vaccination is recommended for all persons aged ≥6 months. To permit time for production of protective antibody levels (*4,5*), vaccination optimally should occur before onset of influenza activity in the community. Therefore, vaccination providers should offer vaccination as soon as vaccine is available. Vaccination should be offered throughout the influenza season (i.e., as long as influenza viruses are circulating in the community).

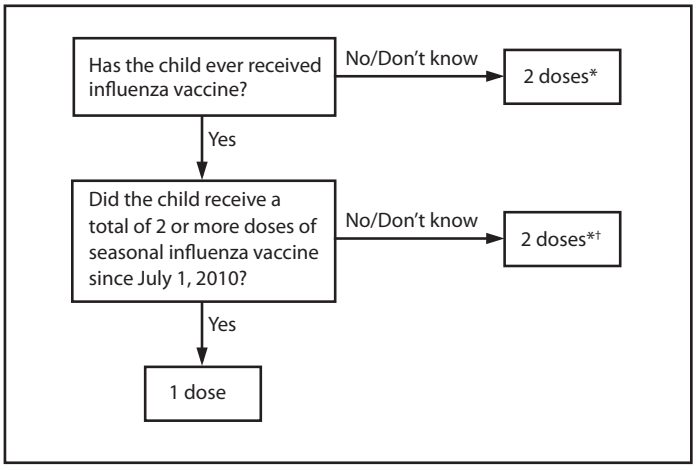
Vaccine Dose Considerations for Children Aged 6 Months Through 8 Years

Children aged 6 months through 8 years require 2 doses of influenza vaccine (administered a minimum of 4 weeks apart) during their first season of vaccination to optimize immune response. In a study of children aged 5 through 8 years receiving trivalent inactivated influenza vaccine (TIV) for the first time,

the proportion of children with protective antibody responses was significantly higher after 2 doses compared with a single dose (*6*). Several studies have indicated that the time interval between two initial doses (from 4 weeks up to 1 year) of the same antigen might not be critical (*7–9*). However, because of the antigenic novelty of the 2009(H1N1) pandemic virus, which is anticipated to continue circulating during 2012–13, exposure history to this antigen also must be considered. Children who last received seasonal (trivalent) influenza vaccine before the 2010–11 season but did not receive a vaccine containing 2009(H1N1) antigen (either seasonal vaccine since July 2010 or monovalent 2009[H1N1] vaccine) will not have received this antigen. These children are recommended to receive 2 doses this season, even if 2 doses of seasonal influenza vaccine were received before the 2010–11 season. This is illustrated in two approaches for determining the number of doses required for children aged 6 months through 8 years, both of which are acceptable (Figure 1).

1. The first approach takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. This recommendation is harmonized with that of the American Academy of Pediatrics (*10*). This approach has the advantage of simplicity, particularly in settings in which ascertaining vaccination history before the 2010–11 season is difficult. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they received a total of 2 or more doses of seasonal vaccine since July 1, 2010. Children who did not receive a total of 2 or more doses of seasonal vaccine since July 1, 2010, require 2 doses in 2012–13.
2. In settings where adequate vaccination history from before the 2010–11 season is available, the second approach may be used. By this approach, if a child aged 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., either 2010–11 or 2011–12 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2012–13. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they have received any of the following:
   - 2 or more doses of seasonal influenza vaccine since July 1, 2010; or
   - 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or
   - 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010.

FIGURE 1. Influenza vaccine dosing algorithm for aged children 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2012–13 influenza season



* Doses should be administered at least 4 weeks apart.

† For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from before July 1, 2010, is available, if a child aged 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., either 2010–11 or 2011–12 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2012–13. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they have received any of the following: 1) 2 or more doses of seasonal influenza vaccine since July 1, 2010; 2) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 3) 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children for whom one of these conditions is not met require 2 doses in 2012–2013.

Children for whom one of these conditions is not met require 2 doses in 2012–13.

Available Vaccine Products and Indications

Multiple influenza vaccines (with the same antigenic composition) are expected to be available during the 2012–13 season (Table). Current package inserts should be consulted for updated information and description of additional components of various vaccine formulations, indications, contraindications, and precautions.

TIV preparations, with the exception of Fluzone Intradermal (Sanofi Pasteur), should be administered intramuscularly. For adults and older children, the deltoid is the preferred site. Infants and younger children should be vaccinated in the anterolateral thigh. Specific guidance regarding site and needle length for intramuscular administration can be found in ACIP's General Recommendations on Immunization (*11*). For intramuscular TIV preparations, children aged 6 through 35 months receive 0.25 mL per dose; persons aged ≥36 months receive 0.5 mL per dose (Table). Fluzone Intradermal is administered intradermally

TABLE. Influenza vaccine information, by age group — United States, 2012–13 influenza season*

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (μg Hg per 0.5 mL dose)	Ovalbumin content (μg per 0.5mL dose)†	Age group	No. of doses	Route
TIV	Fluzone	Sanofi Pasteur	0.25 mL prefilled syringe	0.0	—§	6–35 mos	1 or 2¶	IM**
			0.5 mL prefilled syringe	0.0	—§	≥36 mos	1 or 2¶	IM**
			0.5 mL vial	0.0	—§	≥36 mos	1 or 2¶	IM**
			5.0 mL multidose vial	25.0	—§	≥6 mos	1 or 2¶	IM**
TIV	Agriflu	Novartis Vaccines	0.5 mL prefilled syringe	0	<0.4	≥18 yrs	1	IM**
TIV	Fluvirin	Novartis Vaccines	0.5 mL prefilled syringe	≤1	≤1	≥4 yrs	1 or 2¶	IM**
			5.0 mL multidose vial	25.0	≤1			
TIV	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	0	≤0.05	≥3 yrs	1 or 2¶	IM**
TIV	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0 mL multidose vial	<25.0	≤0.3	≥18 yrs	1	IM**
TIV	Afluria	CSL Biotherapies (distributed by Merck)	0.5 mL prefilled syringe	0.0	≤1	≥9 yrs††	1	IM**
			5.0 mL multidose vial	24.5	≤1			
TIV high- dose§§	Fluzone High-Dose	Sanofi Pasteur	0.5 mL prefilled syringe	0.0	—§	≥65 yrs	1	IM**
TIV intradermal¶¶	Fluzone Intradermal	Sanofi Pasteur	0.1 mL prefilled microinjection system	0.0 (per 0.1 mL)	—§	18–64 yrs	1	ID
LAIV	FluMist***	MedImmune	0.2 mL prefilled intranasal sprayer	0.0 (per 0.2 mL)	<0.24 (per 0.2mL)†††	2–49 yrs§§§	1 or 2¶	IN

Abbreviations: TIV = trivalent inactivated vaccine; LAIV = live-attenuated influenza vaccine; IM = intramuscular; ID = intradermal; IN = intranasal.

* Vaccination providers should consult Food and Drug Administration–approved prescribing information for 2012–13 influenza vaccines for the most updated information, including indications, contraindications, and precautions.

† Data on maximum ovalbumin content is supplied in package inserts of certain vaccines. Persons with a history of mild allergy to egg (specifically, those who experience only hives) should receive TIV with additional precautions (Figure 2).

§ Information is not included in package insert but is available upon request from the manufacturer, Sanofi Pasteur, by contacting 1-800-822-2463 or mis.emails@sanofipasteur.com.

¶ Figure 1 describes two approaches for determining the number of doses needed for children aged 6 months through 8 years.

** For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

†† Age indication per package insert is ≥5 years; however, the Advisory Committee on Immunization Practices recommends that Afluria not be used in children aged 6 months through 8 years because of increased risk for febrile reactions noted in this age group with CSL's 2010 Southern Hemisphere TIV. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 through 8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, vaccination providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged ≥9 years.

§§ A 0.5-mL dose contains 60 μg of each vaccine antigen (180 μg total).

¶¶ A 0.1-mL dose contains 9 μg of each vaccine antigen (27 μg total).

*** A new quadrivalent formulation of FluMist was approved by the Food and Drug Administration in February 2012. It is anticipated that this formulation will replace the currently available seasonal trivalent LAIV formulation for the 2013–14 season. FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 2 through 4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2 through 4 years should be asked, "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

††† Insufficient data available for use of LAIV in egg-allergic persons.

§§§ Flumist is indicated for healthy, nonpregnant persons aged 2 through 49 years. Persons who care for severely immunosuppressed persons who require a protective environment should not receive FluMist given the theoretical risk for transmission of the live-attenuated vaccine virus.

via a single-dose, prefilled microinjection syringe. The preferred site for administration is over the deltoid muscle.

Age indications for the various TIV products differ. All TIV preparations contain the same quantity of hemagglutinin (15 μg per vaccine virus strain per 0.5 mL dose; 45 μg total), except Fluzone Intradermal and Fluzone High-Dose (Sanofi Pasteur). Fluzone Intradermal is indicated for persons aged 18 through 64 years and contains 9 μg of hemagglutinin per vaccine virus strain (27 μg total) in a 0.1 mL dose. Fluzone High-Dose is indicated for persons aged ≥65 years and contains 60 μg of hemagglutinin per vaccine virus strain (180 μg total) in a 0.5 mL dose. Within specified age indications, ACIP expresses no preference for any given TIV formulation over another.

The intranasally administered live-attenuated influenza vaccine (LAIV), FluMist (MedImmune), is indicated for healthy, nonpregnant persons aged 2 through 49 years. No preference is indicated for LAIV versus TIV in this age group

(*1*). Persons with a history of egg allergy should receive TIV rather than LAIV. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV given the theoretical risk for transmission of the live-attenuated vaccine virus.

Febrile Seizures Associated with TIV and PCV13

Febrile seizures are common in young children. At least one febrile seizure is experienced by 2%–5% of children, and nearly all children who have a febrile seizure recover quickly and are healthy afterwards (*12*). Before the 2010–11 influenza season, an increased risk for febrile seizures after TIV administration had not been observed in the United States (*13,14*). During the 2010–11 influenza season, CDC and the Food and Drug Administration (FDA) conducted enhanced monitoring for febrile seizures after influenza vaccination because of reports of an increased risk for fever and febrile seizures in young children in Australia associated with a 2010 Southern Hemisphere vaccine produced by CSL Biotherapies (up to nine febrile seizures per 1,000 doses) (*15*). Because of the findings in Australia, ACIP does not recommend the U.S.-licensed CSL Biotherapies' TIV, Afluria, for children aged <9 years (*2,16*) (Table).

Surveillance for U.S.-licensed influenza vaccines during the 2010–11 season subsequently detected safety signals for febrile seizures in young children after TIV administration (*17,18*). Further assessment determined that the increased risk was in children aged 6 months through 4 years on the day of vaccination to the day after (the 0–1 day risk window). The risk was higher when children received concomitant PCV13 (i.e., when the two vaccines are administered at the same healthcare visit) and peaked at approximately age 16 months (*18*). No increased risk was observed in children aged ≥5 years after TIV or in children of any age after LAIV. The magnitude of the increased risk for febrile seizures in young children in the United States (<1 per 1,000 children vaccinated) was substantially lower than the risk observed in Australia in 2010 (*15*).

After evaluating the data on febrile seizures from the 2010–11 influenza season and taking into consideration benefits and risks of vaccination, no policy change was recommended for use of TIV or PCV13 for the 2011–12 season (*16,19,20*). Surveillance data on febrile seizures in young children after administration of influenza vaccine for the 2011–12 influenza season (same vaccine formulation as 2010–11) were consistent with those from the 2010–11 influenza season (CDC, unpublished data, 2012). No changes in the use of TIV or PCV13 are recommended for the 2012–13 influenza season. As stated previously, ACIP does not recommend the U.S.-licensed CSL Biotherapies' TIV, Afluria, for children aged <9 years (*2,16*) (Table).

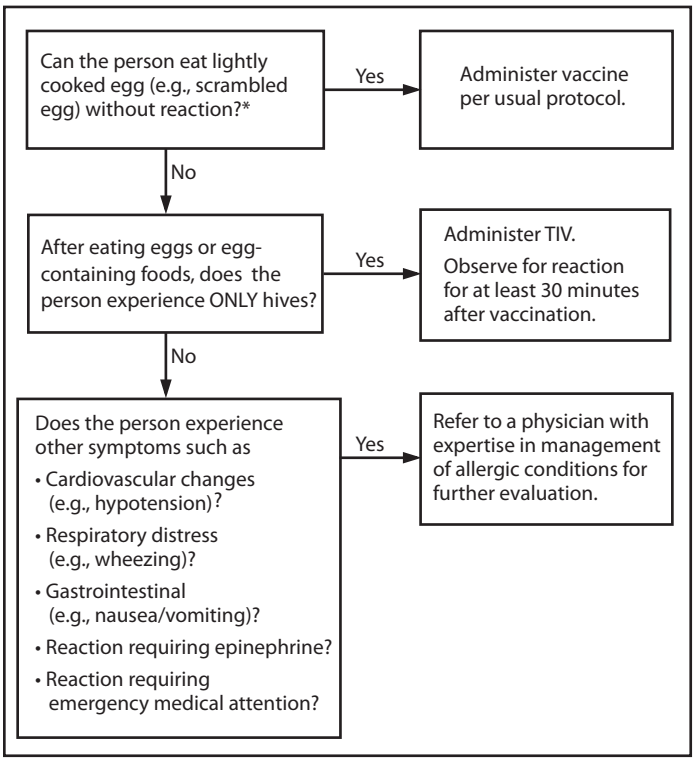
Influenza Vaccination of Persons with a History of Egg Allergy

Severe allergic and anaphylactic reactions can occur in response to a number of influenza vaccine components, but such reactions are rare. All currently available influenza vaccines are prepared by means of inoculation of virus into chicken eggs. The use of influenza vaccines for persons with a history of egg allergy has been reviewed recently by ACIP (*16*). For the 2011–12 influenza season, ACIP recommended that persons with egg allergy who report only hives after egg exposure should receive TIV, with several additional safety measures, as described in this document. Recent examination of VAERS data indicated no disproportionate reporting of allergy or anaphylaxis after influenza vaccination during the 2011–12 season (*21*). For the 2012–13 influenza season, ACIP recommends the following:

1. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine, with the following additional safety measures (Figure 2):
   a) Because studies published to date involved use of TIV, TIV rather than LAIV should be used (*22*);
   b) Vaccine should be administered by a health-care provider who is familiar with the potential manifestations of egg allergy; and
   c) Vaccine recipients should be observed for at least 30 minutes for signs of a reaction after administration of each vaccine dose (*22*).

   Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary (*22*).
2. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, particularly those that occurred immediately or within a short time (minutes to hours) after egg exposure, are more likely to have a serious systemic or anaphylactic reaction upon reexposure to egg proteins. Before receipt of vaccine, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment (Figure 2).

FIGURE 2. Recommendations regarding influenza vaccination for persons who report allergy to eggs — Advisory Committee on Immunization Practices, United States, 2012–13 influenza season



Abbreviation: TIV = trivalent inactivated vaccine.
* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

3. All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available. ACIP recommends that all vaccination providers should be familiar with the office emergency plan (*11*).
4. Some persons who report allergy to egg might not be egg-allergic. Those who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (*23*). Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg proteins.
5. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to future receipt of the vaccine.

Quadrivalent Influenza Vaccines

All currently available influenza vaccines are trivalent and contain A(H1N1), A(H3N2), and B viral antigens. There are two antigenically distinct lineages of influenza B viruses referred to as Victoria and Yamagata lineages (*24*). Immunization against B virus strains of one lineage provides limited cross-protection against strains in the other lineage (*25*). Because of this and the difficulty of predicting which B virus lineage will predominate during a given season, inclusion of a second influenza B vaccine virus strain in seasonal influenza vaccines has been proposed. A recent analysis indicates that the impact of such a quadrivalent vaccine could result in a modest reduction in influenza-associated outcomes, depending upon adequate vaccine supply, coverage, effectiveness, and incidence of influenza associated with the two B lineages (*26*).

In February 2012, FDA approved a new seasonal quadrivalent LAIV, FluMist Quadrivalent (MedImmune). This vaccine currently is not anticipated to be available until the 2013–14 influenza season, at which time it is expected to replace the currently available seasonal trivalent FluMist formulation (Table). Inactivated quadrivalent influenza vaccines currently are in development. These vaccines will be addressed in the ACIP influenza statement as they are approved and become available commercially.

Reported by

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Acknowledgments

Members of the Advisory Committee on Immunization Practices; member roster for July 2011–June 2012 available at http://www.cdc.gov/vaccines/recs/acip/members-archive/07-2011-06-2012.htm.

References

1. CDC. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR 2010;59(No. RR-8).
2. CDC. Update: recommendations of the Advisory Committee on Immunization Practices (ACIP) regarding use of CSL seasonal influenza vaccine (Afluria) in the United States during 2010–11. MMWR 2010; 59:989–92.
3. Food and Drug Administration. Summary minutes: Vaccines and Related Biological Products Advisory Committee, February 28–29, 2012. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2012. Available at http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvaccinesandotherbiologics/vaccinesandrelatedbiologicalproductsadvisorycommittee/ucm296193.pdf. Accessed August 10, 2012.

4. Gross PA, Russo C, Dran S, Cataruozolo P, Munk G, Lancey SC. Time to earliest peak serum antibody response to influenza vaccine in the elderly. Clin Diagn Lab Immunol 1997;4:491–2.
5. Brokstad KA, Cox RJ, Olofsson J, Jonsson R, Haaheim LR. Parenteral influenza vaccination induces a rapid systemic and local immune response. J Infect Dis 1995;171:198–203.
6. Neuzil KM, Jackson LA, Nelson J, et al. Immunogenicity and reactogenicity of 1 versus 2 doses of trivalent inactivated influenza vaccine in vaccine-naive 5–8 year-old children. J Infect Dis 2006;194:1032–9.
7. Englund JA, Walter EB, Fairchok MP, Monto AS, Neuzil KM. A comparison of 2 influenza vaccine schedules in 6- to 23-month-old children. Pediatrics 2005;115:1039–47.
8. Walter EB, Neuzil KM, Zhu Y, et al. Influenza vaccine immunogenicity in 6- to 23-month-old children: are identical antigens necessary for priming? Pediatrics 2006;118:e570–8.
9. Englund JA, Walter EB, Gbadebo A, et al. Immunization with trivalent inactivated influenza vaccine in partially immunized toddlers. Pediatrics 2006;118:e579–85.
10. American Academy of Pediatrics. Recommendations for the prevention and control of influenza in children, 2012–2013. Pediatrics 2012. In press.
11. CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60(No. RR-2).
12. Steering Committee on Quality Improvement and Management, Subcommittee on Febrile Seizures, American Academy of Pediatrics. Febrile seizures: clinical practice guideline for the long-term management of the child with simple febrile seizures. Pediatrics 2008;121:1281–6.
13. Hambidge SJ, Glanz JM, France EK, et al. Safety of trivalent inactivated influenza vaccine in children 6 to 23 months old. JAMA 2006; 296:1990–7.
14. Greene SK, Kulldorff M, Lewis EM, et al. Near real-time surveillance for influenza vaccine safety: proof-of-concept in the Vaccine Safety Datalink Project. Am J Epidemiol 2010;171:177–88.
15. Australian Government Department of Health and Ageing, Therapeutic Goods Administration. Investigation into febrile reactions in young children following 2010 seasonal trivalent influenza vaccination. Woden, Australian Capital Territory: Australian Government Department of Health and Ageing; 2010. Available at http://www.tga.gov.au/pdf/alerts-medicine-seasonal-flu-100702.pdf. Accessed August 10, 2012.
16. CDC. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. MMWR 2011;60:1128–32.
17. Leroy Z, Broder K, Menschik D, Shimabukuro T, Martin D. Febrile seizures after 2010–2011 influenza vaccine in young children, United States: a vaccine safety signal from the vaccine adverse event reporting system. Vaccine 2012;30:2020–3.
18. Tse A, Tseng HF, Greene SK, et al. Signal identification and evaluation for risk of febrile seizures in children following trivalent inactivated influenza vaccine in the Vaccine Safety Datalink Project, 2010–2011. Vaccine 2012;30:2024–31.
19. Advisory Committee on Immunization Practices. General recommendations: febrile seizures. Influenza session. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 2011.
20. CDC. Prevention of pneumococcal disease among infants and children—use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010;59 (No. RR-11).
21. Advisory Committee on Immunization Practices. Update on influenza vaccine safety monitoring. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 2012. Available at http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-jun12/03-influenza-shimabukuro.pdf. Accessed August 10, 2012.
22. Kelso JM, Greenhawt MJ, Li JT. Adverse reactions to vaccines practice parameter 2012 update. J Allergy Clin Immunol 2012;130:25–43.
23. Erlewyn-Lajeunesse M, Brathwaite N, Lucas JS, Warner JO. Recommendations for the administration of influenza vaccine in children allergic to egg. BMJ 2009;339:912–5.
24. McCullers JA, Saito T, Iverson AR. Multiple genotypes of influenza B virus circulated between 1979 and 2003. J Virol 2004;78:12817–28.
25. Belshe RB, Coelingh K, Ambrose CS, Woo JC, Wu X. Efficacy of live attenuated influenza vaccine in children against influenza B viruses by lineage and antigenic similarity. Vaccine 2010;28:2149–56.
26. Reed C, Meltzer MI, Finelli L, Fiore A. Public health impact of including two lineages of influenza B in a quadrivalent seasonal influenza vaccine. Vaccine 2012;30:1993–8.

Adult - Refusal to Stay After Receiving a Vaccine

Name of client: _____ Date vaccine administered: _____

Name of vaccine: _____ Time vaccine administered: _____

- A healthcare professional has informed me that I should remain for 15 minutes after receiving influenza vaccine in order to be observed for signs and symptoms of an immediate adverse reaction.
- I have also been advised of the risks of an allergic reaction to the vaccine, including the inability to breathe.
- I acknowledge that I have been properly informed about the potential side effects of taking the vaccine and the risks of leaving before the recommended fifteen minutes observation.
- Notwithstanding the recommendations, and mindful of the potential adverse consequences from taking the vaccine, I decline to remain for a fifteen minute period of observation.
- I assume full responsibility for any adverse consequences which arise from my leaving prior to the recommended observation period, including a potential severe allergic reaction to the vaccine which may hinder my ability to breathe and may require emergency care.

_____ _____ _____

Signature of Adult Client Date Time

_____

Printed Name of Adult Client

_____ _____

Signature of Clinic Authority/Vaccinator Date

Reference: Epidemiology and Prevention of Vaccine-Preventable Diseases, 12th Edition; U.S. DHHS, CDC; May, 2011, Appendix D-3.

Reviewed and Revised: August 6, 2012

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Model Plan: Reporting Adverse Events Following Influenza Vaccination

School Located Vaccine Clinic (SLVC) staff should report any vaccine adverse events occurring in the SLVC setting to the Vaccine Adverse Event Reporting System (VAERS).

Background
VAERS, administered by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), is a safety surveillance program that collects information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the US.

- Each report provides valuable information that is added to the VAERS database that supplies the information needed for evaluation of vaccine safety.
- Anyone can file a VAERS report; including health care providers, vaccine recipients and parents or guardians.
- Vaccine recipients and parents/guardians should consult their health care provider if they suspect an adverse event associated with the vaccine.
- FDA and CDC do not provide individual medical treatment, advice, or diagnosis.

What can be reported to VAERS?

- Report any clinically significant medical event that occurs after vaccination, even if you are not sure whether the vaccine caused the adverse event.
- The National Childhood Vaccine Injury Act requires health care providers to report any adverse event listed by the vaccine manufacturer as a contraindication to receive additional doses of the vaccine and any adverse event listed in the "VAERS Table of Reportable Events Following Vaccination" that occurs within the specified time period after vaccination.

How to report to VAERS:

- **Anyone may report** but preferably the SLVC Vaccinator or Clinic Authority should complete the VAERS report if the event occurs in the SLVC setting.
- Parents and adults vaccinated in the SLVC setting should be instructed to contact their healthcare provider if they are experiencing a possible vaccine associated adverse event after leaving the SLVC.
    - Download the VAERS Form (PDF-98.5 KB).
    - Request a VAERS Form by sending e-mail to info@vaers.org, by calling (800) 822-7967, or by faxing a request to (877) 721-0366.
    - Before you begin review the Instructions for Completing the VAERS Paper Form.
    - Fax a completed VAERS Form to (877) 721-0366.
    - Mail a completed VAERS Form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. A pre-paid postage stamp is included on the back of the form.
    - Federal CDC will send you a confirmation after the report is received.

If you have additional questions on VAERS Reporting call Maine Immunization Program at (800) 867-4775

Reviewed and Revised: 08/21/2012

School-Located Vaccine Clinics for Influenza

2012-2013 SLVC TOOLKIT

Part 4: MODEL EMERGENCY PLANS

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4.1 Model Plan for Anaphylaxis
4.2 Model Plan for Administration of Epinephrine and Benadryl
4.3 Model Plan for Evaluation and Follow-up of an Exposure to Blood and Other Potentially Infectious Material
4.4 Model Plan for Prevention of Post-Immunization Syncope-Related Injuries

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services

Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Model Plan: Emergency Plan for Anaphylaxis

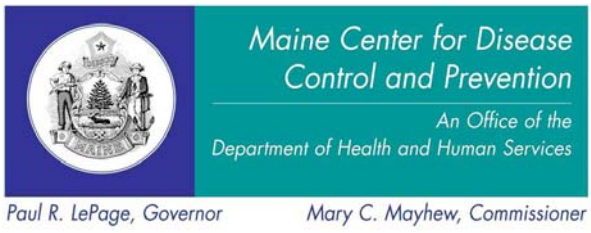
I. Purpose:

To define allergic hypersensitivity to drugs administered by parenteral route as well as the emergency management that is to be provided by the School Vaccine Provider.

II. Policy:

- A plan for contacting emergency medical services that are available in the area shall be established prior to starting any clinic.
- The plan shall include local emergency telephone numbers.
- Recipients of medication, vaccine, or biologicals administered by parenteral route shall be requested to remain on site for a minimum of 15 minutes for signs of hypersensitivity or anaphylactic reaction. Symptoms of anaphylaxis usually begin within 15 minutes after administration of the drug, and intervention should be implemented immediately. A School Vaccine Provider shall remain on site for 15 minutes after each drug is administered parenterally.
- Individuals with symptoms categorized as mild may only require close monitoring on site with notice to their health care provider. Individuals with symptoms that progress shall require intervention including the administration of epinephrine. Refer to the Protocol: Administration of Epinephrine and Benadryl.

Reviewed and Revised: 8/6/2012



Model Plan:
Administration of Epinephrine and Benadryl

NOTE:

The signs and symptoms of anaphylactic shock are: hypotension, respiratory distress such as laryngeal edema, dyspnea, wheezing, a sense of retrosternal pressure or tightness, rapid and/or irregular pulse, urticaria, loss of consciousness, agitation, faintness, burning and/or itching eyes, tearing, congestion and itching nose, rhinitis, nausea, vomiting, abdominal pain, diarrhea, flushed skin, general itching, non-pruretic swelling of extremities as well as the face and perioral or periorbital regions, and/or a sense of uneasiness.

- After an injection of medication and/or vaccine it is determined that the individual has symptoms categorized as mild, the client may only require close monitoring on site with notice to their health care provider..

- Using clinical judgment, when the individual's symptoms progress to those of anaphylactic shock, School Vaccine Providers shall initiate the emergency procedure for the administration of Epinephrine and Benadryl.

Special Instructions:

1. Equipment needed includes:

   2 ampules Epinephrine (adrenaline) 1:1000
   1 vial of Benadryl (diphenhydramine) 50mg/ml
   4 TB syringes
   (2) 3cc syringes (w/needle-22-25 ga, 1-1.5" length)
   Alcohol swabs
   B/P cuff and stethoscope
   CPR mask

2. All School Vaccine Providers are required to be trained in Health Care Provider cardiopulmonary resuscitation (CPR).

3. In the event of a medical emergency during a clinic session, School Vaccine Providers shall activate emergency medical services and notify the responsible health care provider and/or call an ambulance or other local emergency medical services.

4. School Vaccine Provider staff shall apply CPR if the situation warrants it, unless there is a "Do Not Resuscitate" order in place. The school disclaims any liability for misapplication of this knowledge by the School Vaccine Provider.

In an emergency:

1. **Call for assistance**
2. **Notify local emergency medical services**
3. **Establish and maintain an airway**

To administer Epinephrine and Benadryl, follow the steps below:

1. **Administer Epinephrine (per dosage chart/guidelines)**
2. **Administer Benadryl (per dosage chart/guidelines)**

A. Using a tuberculin (1cc)-syringe draw up only the amount of Epinephrine needed, based on the weight of the child or the dosage amount for an adult.

B. Administer the Epinephrine subcutaneously. NOTE: DO NOT GIVE if symptoms of angina are present.

Epinephrine Dosage Guidelines:*

Epinephrine (Adrenaline Chloride) 1:1000

0.1cc for children < 20 lbs. (0-12 months of age)

0.2cc for children 20 - 45 lbs. (1-4 years old)

0.3cc for children > 45 lbs. (> 4 years of age)

0.3cc for adults

C. Administer the Benadryl deep I.M. in a large muscle.

Benadryl Dosage Guidelines

****Adult:** Benadryl 50mg. Deep I.M. in large muscle

*****Pediatric Patients other than premature infants or neonates:** Benadryl 1mg/kg Deep IM in large muscle

D. Observe the clinical condition of the individual including the apical pulse rate and rhythm, respiratory rate, blood pressure, and level of consciousness. Monitor the blood pressure and pulse every 2-5 minutes until stable. Also note a change in any of the symptoms or the development of new symptoms.

E. If symptoms persist, give a second dose of Epinephrine in 15 minutes, using a second ampule of Epinephrine. **Do not repeat more than one time.**

F. If the individual exhibits signs of shock treat them by having them lie in a supine position with their legs elevated, keeping them warm with blankets, if necessary.

G. Reassure the individual and the family (if present).

H. If CPR becomes necessary, institute as per current CPR protocols The responder must be certified to conduct CPR.

*American Academy of Pediatrics, Abbott Laboratories, American Hospital Formulary Service, Mosby's Nursing Drug Reference
** Nursing 2006 Handbook, 26rd edition . New York: Lippincott Williams & Wilkins.
*** Nelson's Textbook of Pediatrics, 15th edition. Philadelphia: Saunders.

Reviewed and Revised: 8/6/2012

Maine Center for Disease Control and Prevention
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Model Plan: Evaluation and Follow-up of an Exposure to Blood and Other Potentially Infectious Material

Special Instructions:

1. Any Vaccinator who sustains a needle stick injury or other parenteral or mucosal exposure to blood or other potentially infectious material (OPIM) shall immediately wash the affected area with soap and water. If washing facilities are not available the School Vaccinator shall use the alcohol based hand gel and paper towels. Mucous membranes should be flushed with water[1].

2. The Vaccinator shall proceed to the closest Urgent Care / Emergency Department for post exposure evaluation and treatment if indicated. NOTE: Postexposure prophylaxis should be initiated as soon as possible, preferably within hours rather than days of exposure. [2]
    i. The Vaccinator who has sustained the exposure with blood or OPIM may enlist the assistance of personnel at the clinic site if needed.

3. The employer of the Vaccinator shall be notified as soon as possible, within 24hours, of the exposure

4. The Centers for Disease Control and Prevention (CDC) recommends that the post exposure evaluation and follow-up includes[1]:
    i. Documentation of the routes and circumstances of the exposure.
    ii. Identification and testing of the source individual, if possible, in accordance with state laws. If the source person is known, the source person may be asked to voluntarily submit to a blood test.

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[1] CDC.Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HVC, and HIV and Pecommendations for Postexposure Prophylaxis.MMWR.2001.50(RR11);1-42

[2] CDC.Updated U.S. Public Health Service Guidelines for Management of Occupational Exposures to HIV:Recommendations for Postexposure Prophylaxis.MMWR 2005;54 (RR09);1-17

a. Under certain circumstances, and in accord with M.R.S.A. 19203-C, a source that has refused to voluntarily submit to a blood test may be required by a court order to do so.

iii. Testing of the exposed employee's blood for HBV, HVC and HIV.

a. The HIV blood test may consist of specimens drawn at the time of exposure and at recommended intervals up to 6 months. Counseling occurs according the state law M.R.S.A. 19203, B., or when requested.

iv. Post-exposure prophylaxis as ordered by the physician.

v. Post-exposure counseling, as indicated for the employee.

a. If the employee declines evaluation or treatment they shall sign a declination form that indicates that the employee has been counseled regarding the risks, treatment has been offered and the employee refused the evaluation and treatment.

5. The school shall maintain strict confidentiality in accord with statutes, policies and procedures. The employer of the school vaccine provider shall maintain accurate, confidential, separate records for each employee with an occupational exposure. These records shall be maintained consistent with the maintenance of OSHA records. These records shall be maintained for a period of 30 years after the termination of the employee.

Reviewed and Revised: 8/6/2012

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Model Plan: Prevention of Post-Immunization Syncope-Related Injuries

Syncope, also called fainting, is a temporary loss of consciousness resulting from decreased blood flow to the brain. Immunization providers should be aware of the potential for syncope associated with vaccination, particularly among adolescents. Syncope after vaccination itself is usually not a serious event, and patients generally recover within a few minutes. The main concern is injury, especially head injury. Vaccine clinic staff should take appropriate measures to prevent syncope and to readily respond to the vaccinee who feels faint.

Steps to Prevent Syncope-Related Injuries

- Make sure the patient is either seated or lying down at the time of vaccination.
- Observe patients for 15 minutes after vaccination for signs and symptoms that commonly precede syncope, such as weakness, dizziness, light-headedness, nausea, sweatiness, coldness of the hands or feet, paleness or visual disturbances.
- If vaccinee is experiencing possible signs or symptoms of fainting, take the following steps to prevent syncope and injury from falling:
  - ✓ Have the person sit or lie down immediately
  - ✓ Have the person lie flat or sit with head between knees for several minutes
  - ✓ Loosen any tight clothing and maintain an open airway
  - ✓ Apply cool, damp cloths to the patient's face and neck
  - ✓ Observe the person until symptoms completely resolve
- If vaccinee falls but does not experience loss of consciousness:
  - ✓ Check the vaccinee to determine if injury is present before attempting to move him/her
  - ✓ Place patient flat on back with feet elevated
  - ✓ Observe the person until symptoms completely resolve
- If vaccinee loses consciousness:
  - ✓ Check the vaccinee to determine if injury is present before attempting to move him/her
  - ✓ Place patient flat on back with feet elevated
  - ✓ Maintain an open airway
  - ✓ Call 911 if vaccinee does not recover immediately

References:

The Children's Hospital of Philadelphia. Vaccine Update for Healthcare Providers. Technically speaking: Guidance for preventing fainting and associated injuries after vaccination. Available at: http://www.chop.edu/professionals/vaccine-healthcare-providers/technically-speaking/. Accessed on 6/6/2012.

CDC. General Recommendations on Immunization: A Report of the Advisory Committee on Immunization Practices. *MMWR* 2011; 60(RR02):1-60.

CDC. Vaccine Safety: Fainting (Syncope) After Vaccination. Available at: http://www.cdc.gov/vaccinesafety/Concerns/syncope.html. Accessed on 6/4/2012.

Immunization Action Coalition. Medical Management of Vaccine Reactions in Children and Teens. Available at: http://www.immunize.org/catg.d/p3082a.pdf. Accessed on 6/4/2012.

School-Located Vaccine Clinics for Influenza
2012-2013 SLVC TOOLKIT

Part 5: VACCINE STORAGE AND HANDLING

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5.1 Proper Maintenance and Storage of Vaccine
5.2 SLVC Checklist for Safe Vaccine Handling and Storage
5.3 Transportation of Small Quantities of Influenza Vaccine
5.4 Transportation of Large Quantities of Influenza Vaccine

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services

Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Proper Maintenance and Storage of Vaccine by School Nurses

Special Instructions:

NOTE: The refrigerator must be designated for vaccines, medications and biologicals only. No food or beverage is allowed to be stored in them.

1. One School Nurse and a backup person shall be assigned the responsibility for the proper handling and storage of vaccines kept in school offices.

2. Each location that stores vaccine shall have a working refrigerator and a certified calibrated thermometer suitable for checking internal temperatures of the refrigerator. The refrigerator thermometer must be able to record temperatures at or above 35^0 F- 46^0 F (2-8^0 C).

3. Refrigerator temperature should be maintained between 35° and 46° F. The temperature of the refrigerator must be checked each workday at the beginning of the day and at the end of the day. The temperatures shall be recorded on the log sheets that are obtained from the Maine Immunization Program and placed on or near the refrigerator. Each log shall be maintained by the school for 3 years and then destroyed.

4. **Upon arrival** of the vaccine, the designated School Nurse or backup person shall immediately unpack the vaccines and place them in the refrigerator as appropriate. The vaccines shall be stored inside the refrigerator and never placed on the door shelves (there is too much temperature variation when the door is opened). The vaccines shall be placed so that the cool air may circulate around the vaccines. The newest vaccine shall be placed behind any of the same type of vaccine that has an earlier expiration date.

5. The vaccines shall be written into the vaccine record book and added to the supply on hand so that the count in the record book matches the count in the refrigerator Records shall be retained in the office for 3 years and then destroyed.

6. The School Nurse shall rotate the vaccines monthly so that the ones with the earliest expiration dates are placed in the front of the refrigerator and used first.

7. Ice packs shall be placed inside the freezer to help maintain the temperature when the door is opened.

8. Bottles of cold water shall be placed to line the inside walls of the refrigerator and on the door shelves in order to maintain the internal temperature of the refrigerator when the door is opened.

9. The School Nurse shall place a **"Do Not Disconnect"** sign on each refrigerator and circuit breaker. The electrical connection shall be protected from accidental disconnect by either a protected location or protective plug cover.

10. If the temperature of the refrigerator is recording above or below listed temperatures, the School Nurse discovering a refrigerator or freezer out of temperature range shall:

    - Label the vaccine that it has been stored out of range and not to use the vaccine until given the permission to use from the manufacturer.
    - Notify the Manufacturer of the product for instructions in handling the vaccines (contact numbers below). Contact the Maine Immunization Program, if obtained from the Maine Immunization Program,

11. In the event of an extended power outage the School Nurse shall follow the procedure for extended power outages.

Influenza 2012-2013 Season Manufacturer Contact Information

Manufacturer	Phone Number	Products
GlaxoSmithKline	866-475-8222	Fluarix and FluLaval
Medimunne	877-633-4411	Flumist
Sanofi- Pasteur	800-822-2463	Flu-zone including High Dose

Maine Center for Disease Control Immunization Program: 287-3746 or 1-800-867-4775

Revised: 8/13/2012

School-based Vaccine Clinic Checklist for Safe Vaccine Handling and Storage

Here are the 17 most important things you should do to safeguard your vaccine supply. Are you doing them all?

✓

___ 1. We have a school nurse or a designated person in charge of the handling and storage of our vaccines.
___ 2. We have a back-up person in charge of the handling and storage of our vaccines.
____3. A vaccine inventory log is maintained that documents:
_____ Vaccine name and number of doses received
_____ Date the vaccine was received
_____ Arrival condition of vaccine
_____ Vaccine manufacturer and lot number
_____ Vaccine expiration date
____ 4. Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer.
____ 5. We do NOT store any food or drink in the refrigerator.
____ 6. We unpack vaccine immediately upon arrival and place it in the refrigerator.
____ 7. We store vaccines in the middle of the refrigerator, and NOT in the door.
____ 8 .We check vaccine expiration dates before use.
____ 9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
____10. We always keep a certified calibrated thermometer in the refrigerator that can record temperatures at 35-46°F.
____11. The temperature in the refrigerator is maintained at 35–46ºF.
____12. We use bottles of cold water to line the inside walls of the refrigerator to help maintain cold temperatures.
____13. We post a temperature log on the refrigerator door on which we record the refrigerator temperature twice a day—first thing in the morning and at clinic closing time—and we know whom to call if the temperature goes out of range.
____14. We understand that these temperature logs must be submitted to the Maine CDC Immunization Program at the end of each month with copies maintained by the school for 3 years.
____15. We have a "Do Not Unplug" sign next to the refrigerator's electrical outlet.
____16 .In the event of a refrigerator failure, we take the following steps:
_____ We call the manufacturer first
_____ We notify the Maine CDC Immunization Program.
_____ We label the vaccine stating that it has been stored out of range and not to use the vaccine until given the permission to use from the manufacturer. (this vaccine should be kept in a cold storage unit)
____17. We keep important phone numbers posted where they are easily accessible including:

Manufacturer	Phone Number	Products
GlaxoSmithKline	866-475-8222	Fluarix and FluLaval
Medimunne	877-633-4411	Flumist
Sanofi- Pasteur	800-822-2463	Flu-zone including High Dose
Maine Center for Disease Control and Prevention Immunization Program 287-3746 or 1-800-867-4775		

Adapted with changes from: www.immunize.org/catg.d/p3035.pdf • Item #P3035 (7/08) Revised 8/13/2012
Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

Maine Center for Disease Control and Prevention
An Office of the Department of Health and Human Services

Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Transportation of Small Quantities of Influenza Vaccine

Rationale:

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that the potency is protected by maintaining the cold chain at all times.

If vaccine does not fit in a small cooler using the appropriate layering techniques, use a larger cooler and follow the instructions for Transporting Large Quantities of Vaccine.

It is essential that Influenza Vaccines shall be maintained at 35° - 46° F during transportation.

Special Instructions:

1. Equipment needed:
   1 small vaccine transport ice cooler at room temperature
   2 small refrigerated ice packs
   1 small frozen ice pack
   1 plastic food storage container with cover
   1 certified calibrated digital thermometer with Velcro
   Vaccine
   Diluent if needed

2. At least one day prior to packing, pre-cool the ice/cold packs and temperature probe in the refrigerator.

3. One half hour before leaving for a clinic, it is recommended that the ice packs and the thermometer are placed in the cooler to stabilize the temperature before putting in the vaccine.

4. The cooler shall be packed in the following manner:
   i. 1 small refrigerated ice pack on the bottom of the cooler

ii. 1 covered plastic food storage container with the Vaccine and liquid bottle probe attached to the thermometer inside the container
iii. 1 small refrigerated ice pack
iv. 1 small frozen ice pack (place on top of refrigerated ice pack)

5. The School Vaccine Provider shall pack the vaccine in the cooler the day of the clinic. The Vaccine should remain in their original boxes when transported to the home or clinic site.

6. The School Vaccine Provider shall attach a label to the outside of the container to clearly identify the contents as fragile Vaccines.

7. The certified calibrated thermometer shall be fixed to the outside of the cooler by velcro and used for all temperature readings.

8. The School Vaccine Provider shall record the time and temperature inside the cooler on the *Vaccine Transport Temperature Log.*

9. The School Vaccine Provider shall check the temperature at least hourly to ensure that the cold chain is not broken. Record the time and temperature on the *Vaccine Transport Temperature Log.* Do not open the cooler for hourly temperature readings. Retain these records for 3 years and then destroy.

10. If the temperature of the cooler falls outside of the recommended guidelines the School Vaccine Provider shall take the following actions:

    i. Label the Vaccine that it has been stored out of range

    ii. Notify the Manufacturer of the product for instructions in handling the Vaccine (Manufacturer's contact numbers are listed below)

    iii. If the vaccine was obtained from the Maine Immunization Program notify the Maine Immunization Program at 287-3746

Influenza 2012/2013 Season Manufacturer Contact Information

Manufacturer	Phone Number	Products
GlaxoSmithKline	866-475-8222	Fluarix and FluLaval
Medimunne	877-633-4411	Flumist
Sanofi- Pasteur	800-822-2463	Flu-zone including High Dose

Revised: 8/13/2012

Vaccine Transport Temperature Log

Name of Vaccine placed in transport cooler: _____ Date: _____

Number of vials of Vaccine placed in cooler: _____

Time Placed in transport cooler: _____ AM or PM

Temperature of cooler at time Vaccine leaves office: _____ F Time: _____ AM or PM

Time (Record When Vaccine is Accessed or at Least Hourly)	Cooler Temperature recorded in F	In Range (35° - 46° F)	Out of Range < 35° F OR > 46° F	Action Taken	Signature
Arrival at site TIME:					

Reviewed: 8/13/2012

Maine Center for Disease Control and Prevention
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Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Transportation of Large Quantities of Influenza Vaccine

Rationale:

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times. If vaccine does not fit in a small cooler using the appropriate layering techniques, follow these instructions.

It is essential that Influenza vaccines shall be maintained at 35° - 46° F during transportation.

Special Instructions:

1. Equipment needed:
   - 1 vaccine transport ice cooler at room temperature
   - Ice packs
     - 2 large blue refrigerated ice packs
     - 1 large blue frozen ice pack
     - 5-6 smaller frozen ice packs
   - 1 plastic food storage container with cover
   - 1 certified calibrated digital thermometer with velcro
   - Vaccine
   - Diluent if needed

2. At least one day prior to packing, pre-cool the ice/cold packs and temperature probe in the refrigerator

3. One half hour before leaving for a clinic, it is recommended that the ice packs and the thermometer are placed in the cooler to stabilize the temperature before putting in the vaccine.

4. The cooler shall be packed in the following manner:

i. 1 large blue refrigerated ice pack on the bottom of the cooler
ii. 1 covered plastic food storage container with the vaccine and liquid bottle probe attached to the thermometer inside the container
iii. 1 large blue refrigerated ice pack
iv. 1 large blue frozen ice pack (place on top of refrigerated ice pack)
v. 5-6 smaller frozen ice packs to fill the rest of the cooler

5. The School Vaccine Provider shall pack the vaccine in the cooler the day of the clinic. Vaccine should remain in their original boxes when transported to the clinic site.

6. The School Vaccine Provider shall attach a label to the outside of the container to clearly identify the contents as fragile vaccines.

7. The certified calibrated thermometer shall be fixed to the outside of the cooler by Velcro and used for all temperature readings.

8. The School Vaccine Provider shall record the time and temperature inside the cooler when leaving the office for the clinic. This data shall be recorded on the *Vaccine Transport Temperature Log.*

9. The School Vaccine Provider shall check the temperature at least hourly to ensure that the cold chain is not broken. Record the time and temperature on the *Vaccine Transport Temperature Log.* Do not open the cooler for hourly temperature readings. Retain these records for 3 years and then destroy.

10. If the temperature of the cooler falls outside of the recommended guidelines the School Vaccine Provider shall take the following actions:

    i. Label the vaccine that it has been stored out of range

    ii. Notify the Manufacturer of the product for instructions in handling the vaccine (Manufacturer's contact numbers are listed below)

    iii. If the vaccine was obtained from the Maine Immunization Program notify the Maine Immunization Program at 287-3746.

Influenza 2012/2013 Season Manufacturer Contact Information

Manufacturer	Phone Number	Products
GlaxoSmithKline	866-475-8222	Fluarix and FluLaval
Medimunne	877-633-4411	Flumist
Sanofi- Pasteur	800-822-2463	Flu-zone including High Dose

Vaccine Transport Temperature Log

Name of Vaccine placed in transport cooler: _____ Date: _____

Number of vials of Vaccine placed in cooler: _____

Time Placed in transport cooler: _____ AM or PM

Temperature of cooler at time Vaccine leaves the office for the clinic: _____ F Time: _____ AM or PM

Time (Record When Vaccine is Accessed or at Least Hourly)	Cooler Temperature recorded in F	In Range (35° - 46° F)	Out of Range < 35° F OR > 46° F	Action Taken	Signature
Arrival at clinic site TIME:					

School-Located Vaccine Clinics for Influenza

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Part 6: DOSES ADMINISTERED REPORTING and BILLING FOR VACCINE ADMINISTRATION FEES

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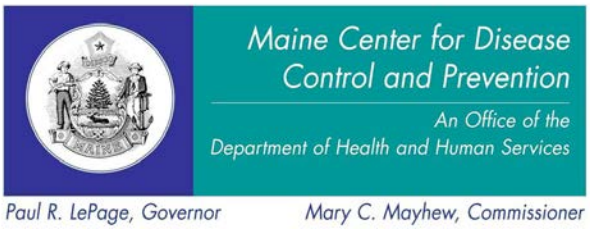
6.1 Doses Administered Reporting
6.2 Roster Billing Instructions for MaineCare Clients
6.3 Billing Private Insurance



Doses Administered Reporting For School Located Vaccine Clinics

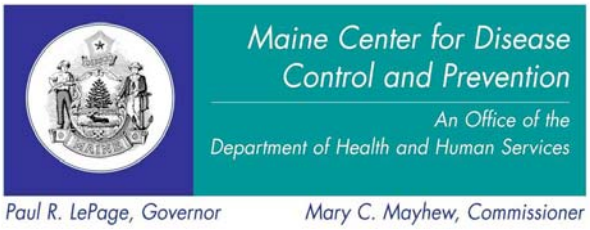
At the conclusion of the vaccine clinic, report clinic information to Clinic Authority and to Maine CDC, as required by the Maine Immunization Program. Doses administered must be entered into ImmPact as soon as possible after the completion of SLVC.

- Use the Mass Immunization to function to record doses administered
  - The Mass Immunziation function enables the SLVC partner to enter multiple vaccine administration records on one single screen.
  - The ledger style process is the same as in previous years with the exception that the dates entered are linked in ImmPact directly to specific clinic dates and no longer need to be entered into the system.

- Delays in doses administered reporting can have multiple effects including:
  - Results in delayed billing and reimbursement for vaccine
  - Inability of the person's healthcare provider to view up-to-date vaccination history, which may lead to double vaccination of the patient.

Links to videocast webinars (hosted on YouTube) with instructions on doses administered reporting can be found on the MIP ImmPact website at

http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/webinars.shtml



Roster Billing for MaineCare Clients
2012-2013 Influenza Season

Maine Center for Disease Control and Prevention (Maine CDC) has been working to find the most efficient process for Roster Billing. In the new process school nurses will be able to locate their MaineCare reimbursement.

Maine CDC and MaineCarehave developed a billing procedure that will not require any extra work from your staff. In the next few months more details will be shared with partners and will be posted on the secure DOE SLVC website and in the *2012-2103 SLVC Toolkit*.

- **School Districts and Vaccinator Partners who claim MaineCare reimbursement through ImmPact will be able to automatically process for reimbursement from Maine Care by following a few steps.**
    - MaineCare staff is creating a process that will accommodate the need to locate this reimbursement as a distinct payment for SLVC activities in the school district business office or the vaccinator partner business office.
    - **Roster billing is acceptable for all influenza presentations, including intranasal.** (10-144 Chapter 101; MaineCare Benefits Manual - Chapter II, Section 3: Ambulatory Care Clinic Services)

The new process will work as follows:

1. Enter the NPI Type 2 number for the organization that will be receiving the reimbursement for the vaccine administration fees, otherwise known as the Pay-to-Provider. This NPI Type 2 number is available at your business office.
    - For School Districts receiving payment:
        - When registering your SLVC clinics you must associate sites in ImmPact with 4 major roles (See SLVC ToolKit, Section 1: Clinic Registration).
        - ***It is essential that the site that you associate as your Vaccinator (this is the new name for the entity that administers the vaccine on-site) is the site that you wish to receive the reimbursements for vaccine***

administration fees. Your School Physician's individual NPI Type 1 number, should already be listed with MaineCare as rendering provider with your organization.

- Your school physician will fulfill MaineCare's requirement of the Supervisory Physician.
    - Your School Physician does not need to be present on-site for SLVCs, but rather be available for consultation as specified in Chapter 90 of the Maine Care Benefits Manual
    - The Supervisory Physician is also able to have other personnel work under their auspices, in accordance with rules approved by their licensing board (MD or DO). Is there a citation for this?

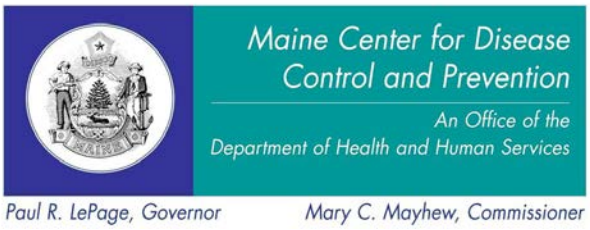
2. MaineCare will add an invoicing category to their remittance process,, specifically for SLCV.

    - This change will allow your payment to include a line item specifically for payment requests that are made from the Maine Immunization Program on your behalf.
    - Once this change in the MaineCare system is completed, you will have a line item indicating that a portion of your MaineCare reimbursement is SLVC-related and the amount of that portion of the remittance.

3. Implementing this change will take approximately 90 days.
    - Until the changes can be made to the invoicing process, the Maine Immunization Program will post a list of NPIs and the reimbursement value made to each NPI to the secure DOE SLVC website for SLVC partners to view their reimbursements.
        - A communication with detailed information about this process will be disseminated to partners in the near future.

We are extremely pleased that MaineCare is able to offer improvement to the SLVC roster billing procedure. The simplified process will help partners to locate the SLVC reimbursements for flu vaccine administration. We hope this helps clarify the MaineCare roster billing process through ImmPact for the 2012-2013 influenza season.

If you have additional questions, please contact Dr. Lauren Ball, Deputy State Epidemiologist, Maine Center for Disease Control and Prevention at lauren.ball@maine.gov or (207) 287-4326.



Billing Private Insurance

2012-2013 Influenza Season

Several SLVC partners are participating in a demonstration project to explore billing private insurance carriers for vaccines administered in the SLVC setting.

Other SLVC partners that are contracted with private insurance carriers, may bill according to contractual arrangement with the carrier.

MEA Benefits Trust will work with school districts to coordinate roster billing for payment of vaccine administration fees for their members.

School-Located Vaccine Clinics for Influenza

2012-2013 SLVC TOOLKIT

Part 7: COMMUNICATIONS

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7.1 Incoming Questions: Email SLVC.DOE@maine.gov

The SLVC.DOE@maine.gov e-mail address has been established specifically for School Nurses and their SLVC partners.

- All incoming questions or comments for the State SLVC Leadership Team should be directed to this email box.
- Please know that communications made via this e-mail address will be responded to as quickly as possible and that responses will be made either individually via e-mail reply or through posting on the SLVC Listserve.

7.2 Outgoing Messages: School Nurse SLVC Listserv

A closed, moderated listserv has been set up for school nurses and Maine CDC SLVC partners.

- Questions received by the SLVC Outreach and Communication Coordinator will be reviewed and responses will be pushed through the SLVC listserv. Communicating through this listserv will allow *all* school nurses to receive answers to questions posed in a timely fashion. This platform will also provide an opportunity to send updates.

As opposed to other Maine School Nurse listserv, this listserv is specific to SLVC and should include only those who may be working on SLVC-related activities.

- Please help us ensure that your school nurse colleagues who are working on SLVC are subscribed to this listserv.
- To get access to this listserv, please inform the SLVC Outreach and Communications Coordinator at SLVC.DOE@maine.gov.

7.3 Secure SLVC Partner Website

A secure webpage has been established for all 2012-2013 Influenza SLVC partners: www.maine.gov/education/sh/slvc

- School Nurses will receive the password to the website on the SLVC listserv.
- School Nurses can share the password with their 2012-2013 SLVC partners.

The following will be posted at this site:

- The 2012-2013 Influenza Toolkit
- School Nurse FAQs
- Other resources

7.4 Promoting Your SLVC: DOE SLVC Poster Template

More information on the Poster Template and its approved uses is forthcoming.

7.5 State SLVC Team Contact Information

DOE:

Nancy Dube, RN, MPH,
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207-624-6688
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Division of Infectious Disease
Maine Center for Disease Control and Prevention
207-287-4326
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Dwight Littlefield, RN MBA
Division of Public Health Nursing
Maine Center for Disease Control and Prevention
207-287-9025
dwight.littlefield@maine.gov

7.6 Other Useful Contacts

Maine CDC Immunization Program: 1-800-867-4775

Maine CDC ImmPact Help Desk: 1-800-906-8754

Maine CDC District Liasons:
District Liaison #1: York: Adam Hartwig (207) 490-4625
District Liaisons #2: Cumberland: Becca Matusovich (207) 797-3424
District Liaisons #3: Western: Jamie Paul (207) 795-4302
District Liaisons #4: Midcoast: Charles Dwyer (207) 596-4278
District Liaisons #5: Central: Paula Thomson (207) 287-2613

District Liaisons #6: Penquis: Jessica Fogg (207) 561-4421
District Liaisons #7: Downeast: Alfred May (207) 263-4975
District Liaisons #8: Aroostook: Stacy Boucher (207) 493-4087
District Tribal Public Health Liaison: Clarrisa Webber (207) 532-2240