Annex 6. Vaccines: Use and Distribution

Responsible Person: Immunizations
Back up: Immunizations

Rationale:

The Maine CDC influenza vaccination effort will reduce outbreaks of influenza and minimize severe disease by offering vaccine to all Maine people, beginning with those in ACIP defined priority groups.

The goal is to create a framework of interagency and community-wide cooperation that contributes to a timely and efficient availability of vaccine against the influenza virus to the people of Maine.

Assumptions:

1. All Maine people, regardless of income and insurance status, will have access to the pandemic influenza vaccine.
2. Vaccine will be shipped in lots of 100 doses.
3. Administration fees will be allowable (90% of health insurance carriers will honor claims by health care providers for compensation for their services in the administration of the vaccine).
4. Vaccine priority groups that are established by the US CDC Advisory Committee on Immunization Practices (ACIP) will be incorporated without modification by the State of Maine.
5. Healthcare providers will be willing to participate in clinics to vaccinate certain priority groups.
6. Occupation health programs will be willing to participate in vaccination clinics.
7. Most public school administrative units and private schools throughout the State will opt to administer the vaccine to their students.
8. The Vaccine Adverse Event Reporting System (VAERS) will be used to identify and manage vaccine adverse effects.
9. U.S. CDC will provide immunization cards with each lot shipment of vaccine.
10. Maine will receive vaccine based on a population pro rata formula, or .004% of the available vaccine.
11. Volunteer vaccinators will be readily available through a system capable of credentialing in adequate numbers to meet the needs of community vaccination clinics.
12. Contract vaccinators and school nurses will be available in sufficient numbers to staff school clinics and mechanisms and funds to obtain these vaccinators will be available.
13. The healthcare system has the capacity to receive, store and transport vaccine for use in school and community clinics.
14. Volunteer community vaccine clinic organizers will be available in sufficient numbers.
15. Designated ship-to sites will be allowed to repeatedly order vaccine and will not be required to receive large shipments or store large quantities for later use.

Overview:

Maine CDC Concept of Operations

A. Vaccine and Supplies Distribution

Vaccine will be distributed to Maine through a nationwide distributor that now handles the distribution of pediatric vaccine for the CDC Vaccines for Children program. This company will directly ship vaccine and associated supplies to designated sites in Maine. Shipments of vaccine are expected to be in increments of 100 doses, however, the total number of ship-to-sites in Maine may not be known in advance. Therefore, it will be necessary to strategically establish ship-to sites around Maine that will be best situated to reach the vaccination settings for the target populations.

The healthcare system has adequate infrastructure and expertise for receiving and storing biologicals such as vaccines, but the healthcare system is not the ideal setting for vaccinating large numbers of people. It is a goal of Maine CDC pandemic response activities to minimize the impact on the healthcare system. To coordinate the distribution and redistribution of vaccine to sites within the State's healthcare infrastructure, the three Regional Resource Centers (RRCs) will work directly with partners in the healthcare system. The RRCs are established regional centers for healthcare preparedness situated within hospitals in the southern (Maine Medical Center) central (Central Maine Medical Center) and northern (Eastern Maine Medical Center) regions of the state. RRCs will work with healthcare partners to establish community vaccine storage sites at several healthcare sites in Maine. Vaccine will also be distributed to public health sites throughout Maine (including Public Health Nursing sites and city health departments) and through the private sector routes that are traditional providers of seasonal influenza vaccine.

B. Vaccine Administration

Vaccine administration in traditional vaccination settings (eg. healthcare, occupational clinics and commercial clinics) is expected to be straightforward. However, there will be a strong need for vaccination in non-traditional settings to reach the defined priority populations. Maine CDC will assign a Vaccine Coordinator for each public health district in Maine. Vaccine Coordinators (VCs) will serve as a coordinator of vaccination clinics in a variety of settings within each of Maine's eight public health districts. VCs will reach out to community organizations within their districts to facilitate vaccination efforts in these non-traditional settings, with the goal of reaching priority populations. A critical aspect of the VC work will be to provide coordination with the RRCs to facilitate the provision of vaccine and vaccinators to vaccination clinics by accessing an established distribution source within the public health or healthcare systems.

C. Vaccination within the Healthcare Setting

The healthcare system typically operates near capacity and influenza is likely to be circulating at the time that vaccine becomes available. Therefore, this plan aims to minimize the use of the healthcare system for vaccine administration. Instead, the healthcare system will focus on vaccinating healthcare workers and patients in priority groups that are in the healthcare system for other reasons. However, some people in vaccine priority groups are likely to have encounters with the healthcare system that provide opportunities for vaccination. In particular, healthcare workers, pregnant women, young children and people with chronic conditions are likely to encounter opportunities for vaccination within the healthcare system during a vaccination campaign.

Healthcare provider offices that are designated as ship-to sites will have the opportunity to order vaccine for patients in their practice who are in targeted priority groups. Establishment of hospital ship-to sites will be coordinated by the RRCs in each region, and vaccine orders will be placed through the Maine Immunization Program. Vaccine can be administered within that medical practice to priority patients, and reporting of aggregate administration records will be done on a weekly basis to Maine CDC.

Healthcare provider offices that are not designated as ship-to sites will be afforded the opportunity to receive re-distributed vaccine. These healthcare provider offices will also be allowed to administer vaccine to priority patients, and reporting of aggregate administration records to Maine CDC will be required on a weekly basis.

The healthcare workforce will be vaccinated in the healthcare system using vaccine from designated ship-to sites within the healthcare system. Vaccine for healthcare worker vaccination can be obtained from hospital ship-to sites or other sources in the healthcare system. This activity will be coordinated by the RRCs. When vaccination is done in a short-term vaccine clinic style, aggregate administration records for the clinic must be returned to the Maine CDC at the conclusion of each vaccine clinic.

It is the goal for Maine CDC pandemic influenza response activities to minimize impact on the healthcare system, it would be appropriate for the healthcare system to provide targeted vaccine clinics for some priority populations. For example, children under five years of age will be more difficult to reach in clinics outside of the healthcare setting than school-aged children. In addition, parents of younger children will be less likely to consent to vaccination in the childcare setting and childcare providers may be less amenable than schools to offering vaccination clinics, potentially making childcare oriented clinics challenging. Therefore, children under five will be vaccinated in multi-physician vaccine clinics within the healthcare setting. These types of clinics, if run by pediatrician practices, could also address household contacts of children under six months of age and possibly pregnant mothers.

D. Mass Vaccination Program

To reach the largest numbers of people in priority groups, it will be necessary to hold public vaccination clinics in common aggregate settings of priority populations outside of the healthcare setting. There are many significant challenges to vaccination outside of the healthcare setting including clinic organization and management, access to vaccine and maintenance of cold chain and access to vaccinators. Within each public health district, coordination of community vaccination efforts will be done by the District Vaccine Coordinators (VCs). VCs will coordinate access to vaccine for community clinics in coordination with RRCs. While vaccine for these community clinics will be accessed through the healthcare system in many cases, some community vaccine settings may also be direct ship-to sites. This decision will be based on the size of the populations reached and the ability of a particular setting to receive, manage and store vaccine. A limited number of ship-to sites will be reserved for this purpose of shipping outside of the traditional healthcare infrastructure.

District	Vaccine Coordinator	Phone
District 1 – York	Vacant	
District 2 – Cumberland	Becca Matusovich	592-5631
District 3 – Western Maine: Franklin, Oxford, Androscoggin counties	Vacant	
District 4 – Mid Coast: Waldo, Knox, Lincoln, Sagadahoc counties	Charles Dwyer	596-4278
District 5 – Central Maine: Somerset and Kennebec counties	Paula Thompson	592-5634

District 6 – Penquis: Penobscot and Piscataquis counties	Jessica Fogg	592-5633
District 7 – Downeast: Washington and Hancock counties	Al May	263-4975
District 8 – Aroostook	Stacy Boucher	592-5632
Tribal District	Jerolyn Ireland	532-2240, Ext. 15
Tribal District	Clarissa Webber	532-2240

Schools and Childcare Facilities

390,000 people or 64% of the priority population is between the ages of 6mos and 25 years. So school facilities (as well as colleges, universities and residential schools) provide by far the greatest opportunities as administration sites for flu vaccine.

There are 171 Public School Districts, 260 Private schools, 22 School Based Health Centers and 192,000 children in public school (K-12) in Maine. As potential vaccinators, there are 342 School Nurses and 50 PHNs statewide. Most schools have cooperating school physicians.

According to the U.S. Census Bureau's American Community Survey 2005-2007, there are approximately 71,000 children under the age of five in Maine and hundreds of childcare facilities statewide ranging from small in-home daycares to large childcare centers with over 100 children. Large childcare centers would be appropriate settings for vaccination clinics, though there may be barriers associated with mass vaccination in this age group. Multi-physician vaccination clinics within the healthcare setting may be more effective. Such clinics may also help to make the best use of the less abundant single-dose thimerosal free vaccine.

In the event of a influenza pandemic, it is expected that the Governor of Maine will sign a Proclamation of Civil Emergency Due to a Highly Infectious Agent to allow the State to better respond to the potential dangers of flu and to facilitate a statewide vaccination campaign.

Many school districts reported that a concern about potential liability was putting at risk their ability to participate in vaccination clinics. The proclamation protects school districts and other vaccination clinic participants from liability. The proclamation also will provide immunity from tort liability for approved health care workers who administer the flu vaccines. Maine CDC is working with Maine Department of Education (DOE) to assure that all Maine children are offered seasonal (regular) and in the event of a pandemic, the novel influenza vaccine in local schools. The Maine CDC will open a toll free number (1-888-257-0990) staffed 9 am – 5 pm with professionals from Maine CDC and DOE to assist schools and partnering health care providers in this effort. A District Vaccine Coordinator will be referred to those schools and/or health care providers who need more direct assistance in the effort.

College/University/Residential Schools

School-Based Health Centers are appropriate sites for influenza vaccination administration. Colleges, universities and residential schools that have adequate facilities to receive vaccine will be direct ship-to sites and order vaccine from the Maine Immunization Program. Facilities that are not direct ship-to sites will be able to receive vaccine from sites within the healthcare via Vaccine Coordinators. Coordination of vaccine, vaccinators and other resources for this setting will be done by the vaccine coordinators in each district.

Homeless Shelters and Correctional Institutions

Shelters and correctional institutions are considered especially high-risk both because of the potential for residents to have underlying health conditions as well as the close aggregate setting those residents are often in. Because the residents of these facilities are not typically there by choice, the State has a special duty in protecting these populations with vaccination. Vaccine will be accessed by these sites either by designating them as direct ship-to sites or accessed from the healthcare system through several contract agencies such as Visiting Nurses Association (VNA).

Occupational Sites

Occupational settings are a common site for administration of seasonal influenza vaccine each year. Employers that normally offer seasonal influenza vaccine do so either through their own employee health program, or through a contract with a healthcare organization (e.g. VNA, Maxim or workplace health companies). These sites offer an opportunity for efficient vaccine administration because they provide large aggregate groups of people who are accustomed to getting vaccine in this setting along with, in many cases, adequate infrastructure to receive, manage, store and administer vaccine. Workplace health programs that participate in pandemic influenza vaccination while administration is limited to the ACIP priority groups will need to have plans in place to administer vaccine only to people in priority populations. Occupational sites may require little coordination depending on their experience and capabilities. Occupational sites will receive vaccine either as designated ship-to sites, or by receiving vaccine from the healthcare system.

LTC/Skilled Nursing Facilities

This setting is a major site for seasonal influenza vaccination, and therefore could provide an opportunity for efficient and simple mass vaccination requiring only vaccine from Maine CDC. People over 65, regardless of their condition, are not included in ACIP priority groups to receive pandemic influenza vaccine. Therefore, until the priority needs have been met and vaccine has been offered to all people, LTC facilities ill not be used for vaccination. When vaccine is offered to all people, LTC facilities will be able to access vaccine in the healthcare system through RRC coordination. Notably, many LTC facilities are MIP providers and typically receive vaccine from Maine CDC.

Public Vaccine Clinics

Although the major vaccination effort is aimed towards the healthcare and educational systems, Maine CDC wants to ensure that every citizen identified within the ACIP guidelines is able to receive the vaccine free of cost when it becomes available. To meet this need, Vaccine Coordinators in Maine's eight public health districts will coordinate community clinic planning and organization in cooperation with County Emergency Management Agencies, municipalities, local provider offices, and Faith-Based Organizations.

Many hospitals throughout Maine have offered to receive, store, process, and ship vaccine (and ancillary supplies) to local clinics. Some have offered trained medical volunteers to administer vaccine in the community clinics.

The vaccine request procedure for a public clinic will begin by the local clinic organizer contacting their Vaccine Coordinator. The VC will then conduct an intake questionnaire to assess the feasibility of the chosen clinic location as well as the ability to ensure proper cold chain custody during transport to the clinic as well as the ability to ensure cold chain during the clinic. Any public vaccination clinic may need

to request resources and personnel to help organize, plan, and implement such an event. Logistical requests will be handled by County Emergency Management Agencies. County EMA will help clinic organizers access trained volunteers, clinic supplies such as tables, chairs, cots, etc.

Organization and Assignment of Responsibilities

Roles and Responsibilities:

1. **Maine Center for Disease Control & Prevention**

Maine CDC will: take the lead in policy development; collaboration with state and local partners; serve as a clearinghouse for educational and technical materials; supply vaccine and vaccination supplies; establish data management standards; develop technical assistance guidance and provide consultation. Maine CDC staff will be responsible for the following:

- **Vaccine Management** – Coordinate the delivery of influenza vaccine from the supplier to the ship-to sites within healthcare system and community partners in coordination with the VCs and the Regional Resource Centers. This includes ordering vaccines to be shipped to designated sites within the healthcare system as well as monitoring vaccine accountability and ensuring that national reporting requirements are met.

- **Education** – Facilitate the development of appropriate messaging, training, and associated educational materials for distribution to healthcare and community partners. Provide information to the public through mass media, press coverage and direct communication.

- **Reporting** - Utilize the adverse event monitoring system established for all vaccinations provided in the state. Collect doses administered in Maine and report to the CDC's Countermeasure Response Administration System weekly during campaign.

- **Planning** - Provide statewide plan for implementation of mass vaccination efforts.

- **Statewide vaccine coordination –** Provide support and coordination of vaccine administration to priority groups outside of the healthcare system.

  A. Maine CDC Vaccine Coordinators

  - District Vaccine Coordinators (DVC) will serve as the primary point of contact (POC) between community clinic organizers & administrators and the health care system.
  - Responsible for implementing State School Vaccination plans at the local level.
  - Provide information to the public related to influenza vaccination.
  - VCs will identify and prioritize populations to receive influenza vaccine who do not have easy access to vaccine through the health care system. They will work with district and local partners to determine the most efficient means for offering the vaccine to these priority groups.
  - Provide coordination of resources for community vaccine clinics, which includes:
    a. Site identification
    b. Clinic management and organization
    c. Immunizers (with RRCs)
    d. Vaccine (with RRCs)
    e. Prioritize/approve vaccine orders for vaccination clinics

f. Planning at the district level

B. Maine CDC Public Health Nurses

- Provide ship-to sites for receiving and storage of moderate vaccine supplies within capable Public Health Nursing sites.
- Provide PHN Vaccinators for influenza vaccine clinics as resources permit.
- Provide guidance and expertise in transporting vaccine between sites.
- Contribute to the statewide planning process.
- Contribute to planning within district.

C. Maine Regional Resource Centers

- Manage/coordinate healthcare ship-to sites within region.
- Assure redistribution of influenza vaccine to non-ship-to healthcare sites in region, as needed. The RRCs will develop plans for redistributing vaccine to sites unable to receive vaccine shipments directly.
- Assure vaccination of healthcare workers in region. Healthcare workers are a priority group for influenza vaccine. The RRCs will develop plans to assure that healthcare workers including EMS workers are offered the vaccine.
- Provide for receipt, storage and delivery of the vaccine from healthcare system to vaccine clinics.
- Vaccine will be distributed to: hospitals, private providers, schools, large employers, and occupational health.
- Manage access to contract vaccinators for vaccine clinics outside of the healthcare setting.
- If requested, hospitals will hold vaccine for school clinics and distribute as required.

2. Department of Defense, Veterans and Emergency Management (MEMA)

- The Maine Emergency Management Agency will assume a logistical role in vaccine distribution and administration of the influenza vaccine to community clinics.
- MEMA will also provide guidance and assistance to county and local governments, businesses and nonprofit organizations in their efforts to provide protection to citizen and property. The Agency uses strategies such as planning, training, exercise and public education to carry out its mission.

3. Department of Public Safety (State EMS)

- Maine EMS developed a vaccination program to allow Intermediates and Paramedics to give flu vaccinations in their communities
- Anyone wanting to train their personnel can get the program materials through their Regional EMS Office or from Maine EMS.
- The program should be taught by someone experienced with vaccinations (RN, local health officer, etc.) approved by the service and the service medical director accompanied by a Maine EMS I/C to answer EMS related questions. Once an I/C has attended a program, they can teach the program.

- In all cases, vaccinations can only be given by Maine EMS providers during an organized, physician-prescripted event.

4. Not-For-Profit Agencies

- 2-1-1 Maine is part of a national movement to centralize and streamline access to health and human service information and resources. 2-1-1 will provide emergency operations during times of natural and other disasters, include accurate and timely information for preparations, and longer term referral for follow-up services if required. 2-1-1 will also provide valuable information for community planning and for future matching of resource development and unmet needs.

5. ME CDC ICS

In planning for this type of campaign, there will be a number of activities that need to be considered for simultaneous management. With any scale of operation, the operational considerations require careful and ongoing planning with a host of traditional and possibly new partners to accomplish the mission. Many of these activities have interrelated dependencies that require time sequenced completion. Using the objective-based management approach of the Incident Command System (ICS) in planning for and implementation of the campaign will provide a framework that is well suited for ensuring all activities are effectively addressed. Additionally, the expandable nature of ICS will allow for component parts to accomplish objectives for both disease surveillance and management, but also run the vaccination components simultaneously should the need arise to manage a disease response concurrently with a mass vaccination campaign. The Maine CDC ICS structure is designed to manage the vaccination campaign and can be scaled up to encompass additional activities for a possible larger influenza response.

Annex 6. Vaccines: Use and Distribution

Maine Inter-Pandemic Period

Mitigation and Preparedness, Awareness
ME Level 0, I, II

1. Provide annual refresher flu campaign to educate the public on the importance of obtaining an annual flu shot for those over 6 months of age, proper hygiene measures, cough etiquette, and stay home if sick.
2. Work to translate health related informational documents into non-English language.
3. RCCs will work to establish designated hospital ship-to sites around the state that will be best situated to reach the vaccination setting for anticipated target populations.
4. Identify mass vaccination sites.
5. RRCs will work with hospital affiliated partners to establish community vaccine storage sites at several HC sites in the state.
6. Assign a Vaccine Coordinator to each of Maine's 8 public health districts.
7. VCs will work with schools and child care centers, homeless shelters, correctional institutions, occupational sites, LTC/SNFs, and other non-traditional mass vaccination sites preemptively to develop agreements for establishing a vaccination clinic at their site as needed.
8. Plan mechanism for obtaining vaccinators for the clinics.
9. Train school nurses to administer influenza vaccine. Contract with third party HC organizations to administer influenza vaccine in school clinics.
10. Work with Immpact2 to develop additional functionality to track vaccine through the life cycle of ordering, distribution and administration.
11. Distribute cold chain kits to schools, if funding permits.
12. Review consent and screening forms for school clinic toolkit.
13. Assign a PHN as a PH School Clinic Resources Nurse to help school nurses plan and implement influenza clinics.
14. Support and assisting Maine schools in improving their plans to implement school based vaccination clinics.
15. Work with non-health care facilities to develop a plan that ensures safe and proper disposal of sharps containers.
16. Provide guidance to Maine businesses on the development of Continuity of Operations Plans (COOPs).

Maine Pandemic Alert Period

Heightened Preparedness, Standby
ME Levels III, IV

1. Ship-to sites will order vaccine through the Maine Immunization Program.
2. Alert transportation and security agents of pending pandemic.
3. Alert vaccine storage sites to prepare to receive vaccine.
4. Alert RRCs to begin preparations to coordinate distribution and redistribution of vaccine from hospitals to vaccination sites.
5. HC providers that are ship-to-sites will have the opportunity to order vaccine for patients in their practice that are in targeted priority groups.
6. Alert, and begin preparations with school and child care centers, homeless shelters, correctional institutions, occupational sites, LTC/SNFs, and other non-traditional mass vaccination sites for anticipated activation of vaccine clinics.
7. Alert vaccinators to the standby status for activating the vaccination campaign.
8. VCs will provide information to the local public, consistent with the ME CDC and the US CDC.

Maine Pandemic Period

Response, Activate
ME Levels V, IV

1. Vaccine will be distributed to states through a nationwide distributor. The supplier will directly ship vaccine and associated supplies to designated ship-to-sites.
2. RRCs will work with hospital affiliated partners to distribute / redistribute vaccine to vaccination sites including to non-ship-to site medical providers, and selected non-medical locations.
3. VCs will coordinate vaccine clinics in a variety of settings within their districts including vaccination clinics in non-traditional settings in order to reach priority populations.
4. HC settings will focus on vaccinating HC workers and patients in priority groups that are in the HC system.
5. Ship-to medical providers will administer vaccine to priority patients.
6. Non-ship-to providers will have the opportunity to receive redistributed vaccine for administration to their patients in priority groups.

7. Reporting of aggregate vaccine administration records will be done on a weekly basis to the ME CDC.
8. The HC workforce will be vaccinated in the HC system using vaccine from designated ship-to sites.
9. The HC may provide targeted vaccine clinics for some priority populations e.g, children under 5 and household contacts of children under six month in pediatric practices.
10. Governor Proclamation of Civil Emergency which will address concerns about potential liability for school districts and provide immunity from tort liability for approved HC workers.
11. The 211 information line will be activated for emergency operations for accurate and timely information.
12. MEMA will provide logistical support.
13. VCs will provide information to the local public, consistent with the ME CDC and the US CDC.

Maine Post Pandemic Recovery Period

Recovery Activities
ME Levels VII

1. Assess the Mass vaccination program implementation.
2. Examine and report data: number of people vaccinated by age and other demographic elements, number of clinics, number of volunteers, any adverse effects from vaccine or incidents in the process.
3. Debrief response staff
4. Debrief/evaluate strengths and weaknesses with community partners (vaccination sites, vaccinators, HC providers, storage and distribution sites, logistical support)
5. Replenish supplies
6. Prepare/compile financial documentation for state and federal reporting.
7. Participate in AAR process.
8. Identify lessons learned.
9. Develop an Improvement Plan and implement corrective actions.
10. Revise MVP as indicated.

Annex 6. Vaccines: Use and Distribution Summary Matrix

Annex 6 Vaccines: Use and Distribution	**Maine Inter-Pandemic Period: Awareness** **Mitigation/ Preparedness** **ME Level 0, I, II**	**Maine Pandemic Alert Period: Standby** **Heightened Preparedness** **ME Levels III, IV**	**Maine Pandemic Period: Activate** **Response** **ME Levels V, IV**	**Maine Post Pandemic Recovery Period** **Recovery** **ME Levels VII**
Vaccine and supplies distribution	Prepare plans collaboratively with stakeholders →	Order vaccine; prepare to receive, maintain cold chain, and distribute vaccine →	Receive and distribute vaccine and supplies, maintain cold chain →	Evaluate process and revise vaccination plan in collaboration with stakeholders: ordering, receiving and distributing vaccine, maintenance of cold chain, logistics, …
Vaccine administration	Identify sites, develop agreements, develop plans for activation, plan for vaccinators, ensure liability coverage →	Alert vaccine sites to prepare for possible activation, alert vaccinators to standby status, alert logistics support, →	Activate volunteers, establish vaccine clinics, receive vaccine and supplies, administer vaccine first to priority groups them all citizens when vaccine becomes available→	Evaluate process and revise vaccination plan in collaboration with stakeholders: administration sites, volunteers, adequate vaccine/supplies; prepare reports: numbers vaccinated by aggregate and by subgroup, adverse effects, incidents, …

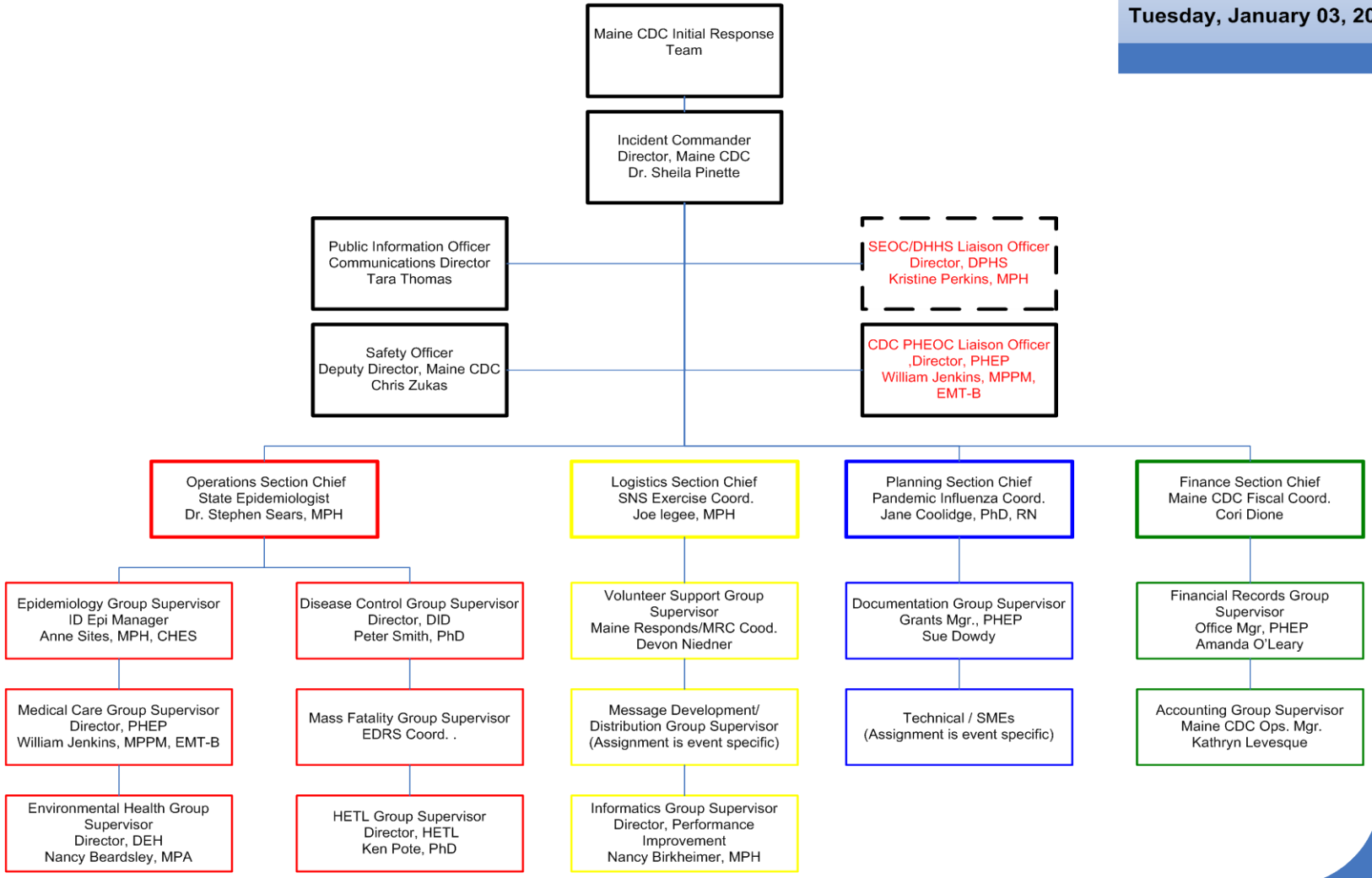
Supplements

A. Maine CDC Incident Command System
B. Vaccine Management
C. Material Management
D. Vaccine Security
E. Vaccine Clinic Operations
F. Adverse Event Medical Management
G. Vaccine Safety
H. Communications
I. Reporting and Data Management
J. Mass Vaccination Clinic:
- **a. Floor Plan**
- **b. Organizational Chart**
- **c. Instructions for Patient Flow**

Supplement A: Maine CDC H1N1 Organizational Structure

Maine CDC All-Hazards Incident Command Structure

Tuesday, January 03, 2012



Supplement B: Vaccine Management

A. General Information

Vaccine accountability will be coordinated with the Maine Immunization Program (MIP). MIP will designate a Vaccine Coordinator and Assistant Vaccine Coordinator who will be responsible for all aspects of the vaccine management process and for training of other staff who will maintain accountability and the cold-chain custody. This responsibility includes:

- Ensuring cold-chain maintenance of vaccine for storage facilities, and while in use in mobile or off-site clinics.
- Managing vaccine logistics to ensure vaccine is available at all vaccination clinic locations while minimizing the risk of wastage.
- Ordering vaccine from the MIP or other designated process as may be needed.
- Assisting in the transfer of vaccine from one location to another.
- Re-allocating vaccine stocks as demand requires between counties.
- Appropriately disposing of empty, wasted, reconstituted/expired, or reconstituted/non-expired (if directed) vaccine vials as instructed.
- Ensure security of the vaccine throughout the vaccine management process.

B. Vaccine Target Groups

The Association of Community Immunization Practices (ACIP) will identify and recommend the priority groups to receive the vaccine based on resultant illness characteristics of the circulating novel virus and as the vaccine becomes available.

C. Vaccine Request Procedures

Pandemic vaccine will not be commercially available as is the case with seasonal influenza vaccine. Therefore, all pandemic vaccine must be requested from designated ship to sites around Maine. The vaccine request procedure from designated ship-to sites will be:

- Complete Provider Agreement Form and return to the MIP.
- Complete a Memorandum of Agreement (MOA) and return to MIP if the requesting provider will redistribute the vaccine.
- Complete a Vaccine Order Form and return to MIP.
- MIP will send the vaccine request form to Supplier.
- The supplier will process the request and ship vaccine directly to the designated ship-to site. (Healthcare system, LTCF, FQHCs etc)
- Providers can place multiple orders for the vaccine.

The vaccine request procedure from designated ship-to sites to community clinics will be:

- A community organizer determines that a vaccination clinic is required (logistics).
- Community organizer contacts their Vaccine Coordinator (VC).
- The VC will conduct an intake assessment of a potential clinics ability to obtain a prescribing physician, has adequate location to hold a clinic, and can ensure cold chain custody is maintained

from the ship-to site to the clinic as well as adequate cold chin during the clinic's operational period.

- VC requests vaccine from a local ship-to site (hospital).
- Vaccine is delivered by third party delivery system or picked up by the community organizer.

D. Ordering Influenza Vaccine

The MIP will ensure that vaccine is readily available. To order vaccine the VCs should use the defined process for ordering. A properly completed form would indicate the total number of doses currently in inventory and the doses requested. The VC must follow these steps:

- Inventory the doses on hand under MIP control and doses dispensed.
- Determine the number of additional doses needed.
- Complete order form in accordance with MIP Provider Agreement Form or designated authority's guidance.
- For purposes of tracking, the vaccine manufacturer and lot number will be associated with the vaccination program

F. Ancillary Vaccination Clinic Supplies and Equipment

The Maine CDC will acquire ancillary supplies and equipment sufficient to administer the number of vaccinations to be given at each vaccination clinic in their geographical area. Maine CDC will develop and disseminate a process for ordering supplies provided with the vaccine as well as other supplies necessary to operate clinics. These ancillary supplies and equipment must be available prior to the operation of vaccination clinics.

Supplement C: Material Management

A. Vaccine Shipping Information

A centralized distributor will prepare vaccines for shipment to the designated ship-to site. Vaccine will be shipped in Styrofoam containers suitable for maintaining the cold-chain environment. The containers will include ice packs to maintain proper temperature; however, the ice packs will not be placed against the vaccine. If needed, the Maine CDC should retain shipping containers for use in transfers of vaccine.

1. Receiving Vaccine at Ship-to Sites

On receipt of vaccines, the Vaccination Coordinator, or his/her designee, must perform the following tasks:

- Inspect the shipment for damage and confirm that the vaccine doses and lot numbers in the shipping boxes match the information printed on the shipping invoice.

- Contact MIP at (207) 287-3746 or designated authority if discrepancies are found between the shipping invoice and the shipped boxes.

- Remove vaccines immediately from shipping container and place in a monitored refrigerator. The temperature of this refrigerator must be 2-8 degrees Celsius (36-46 degrees Fahrenheit).

- The temperature of the refrigerator must be electronically monitored or manually monitored with the temperature recorded early each morning and late each afternoon. If being monitored manually, a calibrated thermometer must be read and recorded twice daily by trained personnel.

2. Ship-to Site to Vaccination Clinic Location

Ensure that appropriate immunization service sites are established. Immunization service sites for vaccine purposes should be permanent storage locations and transfers should take place between sites or locations pursuant to vaccine accountability practices.

Vaccine Coordinators will determine the number of doses needed at a particular vaccination clinic based. The following tasks must be completed by the Vaccine Coordinator for the shipment of vaccine to these vaccination clinic locations:

- The vaccines must be placed in Styrofoam coolers with sufficient ice packs to maintain the cold-chain environment until it arrives at the destination.

- Storage and handling instructions for the vaccine should be reviewed with all staff before they begin their shift.

- Specific security needs for each vaccination clinic must be formally assessed and implemented consistent with local security plans.

- The Vaccination Coordinator or his/her designee will retain all temperature logs relevant to influenza vaccine storage.

B. Storage and Handling

1. Chain of Cold Custody

The influenza vaccine must be managed and maintained in accordance with manufacturer's instructions and CDC guidance.

The Vaccine Coordinator is responsible to ensure cold chain is maintained through proper handling and storage. Local transport and day use require the use of Styrofoam coolers and cold packs. Temperatures in day use containers should be monitored and ice packs replaced if needed. During breaks or lunch the vaccine should be moved to a temporary secure refrigerator.

During day use, medical staff should keep the vaccine in the container/cooler. However, vaccine may remain out of the cooler for the length of the vaccination clinic. It is anticipated that the typical clinic will last from 2-4 hours per session during which vaccines would be continuously administered and can be maintained at ambient temperature. Other than the duration of the vaccination clinic, the vaccine should not be taken out of the cooler and allowed to sit outside for any extended length of time. The vaccine should be returned to the refrigerator when not in use, such as during breaks or lunch.

2. Additional Vaccine Information

Recommendations for the handling and storage of influenza vaccine can be found in the manufacturers package insert. The Maine Immunization Program will advise Vaccine Coordinators of any new vaccine issues.

C. Disposal of Empty, Wasted or Expired Vials

Empty, wasted or expired vials or vials containing wasted or unserviceable vaccine should be placed in sharps container for disposal.

D. Returning/Reallocating Vaccine to Ship-to Sites

Maine CDC will not require unopened vials of vaccine be returned to ship to sites. However, if a decision is made to return unopened vials of vaccine to the ship to site, the VC will implement the following procedures. This section is subject to change based on final federal guidance.

- The Vaccine Coordinator will complete a Vaccine Return Form.
- Vials of unopened vaccine returned to the ship to site in a suitable Styrofoam cooler with cold packs sufficient for maintaining a cold-chain environment.
- Transportation of vaccine from the ship to site to the clinic will be coordinated through the three Maine Regional Resource Centers and VCs, in cooperation with hospitals.
- The Vaccination Coordinator may acquire additional packaging material (i.e., coolers, cold packs, etc.) to ensure that the unopened vials are returned in the appropriate environment from clinic site.
- Information regarding the receipt of vaccine (i.e., clinic address, quantity, lot number, and expiration date) will be checked and the original Vaccine Return Form will be sent to MIP.

E. Additional Information

- Handling Influenza Biomedical Waste Items Materials which may be contaminated and/or present a threat of infection to humans should be disposed as biomedical waste and placed in a sharps container.

Supplement D: Vaccine Security

A. Vaccine Security

- Vaccine storage units will be designated as a secured area consistent with departmental policies and procedures. The area will be secured and access will be limited to only those persons authorized for access.

- Backup power sources (generators) are recommended for all units where vaccine is stored overnight.

- Should backup power sources not be available, the Vaccine Coordinator or clinic provider is responsible for ensuring the clinic has documented procedures for ensuring a cold-chain environment, including the identification of suitable temporary cold storage units which meet the secured area requirements outlined in the departmental policies and procedures.

- Vaccine transportation should be handled in accordance with established Maine Public Health Nursing security procedures.

- Vaccine must not be left unattended during clinic sessions.

Supplement E: Vaccine Clinic Operations

A. General Information

The Vaccine Coordinators are responsible for assuring that all appropriate resources are available at each vaccination clinic location. The clinic should have a vaccination emergency action plan should emergency medical services be needed at a clinic.

If the clinics are restricting vaccination to certain groups, site security should be coordinated with local law enforcement. At a minimum, law enforcement will be required for traffic management.

B. Recruitment

In order for the Influenza Mass Vaccination Campaign to be a success, everyone involved in the process, from recruitment through post-vaccination monitoring, must be diligent in assuring that they have current information, are extremely attentive to detail and follow-up, and maintain close communication with other team members and partners. Maine CDC staff must keep in mind the nature of the initiative and must expect that guidance may be updated as new information and data emerge during implementation. Information is expected to be updated frequently during the planning and implementation of the vaccination campaign.

ACIP defined priority groups will be vaccinated based on vaccine availability. The choice to receive an influenza vaccination is voluntary. The Maine CDC may inform potential vaccinees directly or through partnerships with other agencies and organizations.

The Vaccination Coordinator will assure that participating partner agencies and community vaccination clinic managers have required vaccine information materials so vaccinees are able to make an informed choice. The potential vaccinee will be issued the following appropriate Influenza vaccine information:

- Influenza Vaccine Information Statement (VIS)
- Vaccine Consent Form

C. Vaccination Scheduling

Vaccination clinic locations and schedules must be flexible enough to accommodate requests for staggering staff vaccinations over time.

- The Vaccination Coordinator will facilitate training and insure quality control for hospitals, other healthcare facilities, private providers, and other designated agencies that will conduct influenza immunization clinics at their location.
- Each scheduled clinic shall have a designated clinic manager to coordinate activities and serve as the point of contact for the Vaccination Coordinator.
- The Vaccination Coordinator shall maintain a consolidated list of clinics scheduled within the county, the list shall include the clinic manager, clinic location, clinic times, and target audience.

D. Vaccine Clinic Registration

The clinic intake clerk will:

- Verify potential vaccinee against the list/roster of pre-screened individuals.
- Encourage potential vaccinee to read the Vaccine Information Statement.
- Advise potential vaccinee that there will be an opportunity to discuss any questions or concerns they may have with a medical screener.
- Provide an overview of the vaccination process.
- Advise the potential vaccinee that she/he may withdraw for any reason at any time prior to the point of vaccination.
- Direct the potential vaccinee to the waiting area until called by the medical screener (and project possible wait time).

E. Medical Screening

The medical screening is critical to minimize vaccine risk for vaccinees. Medical screeners must be medically-trained personnel such as physicians, registered nurses, physician assistants, paramedics, licensed practical nurses (see note below) and nurse practitioners.

Note: Direct supervision by a registered nurse or MD should be provided if licensed practical nurses are assigned medical screening of influenza vaccinees. It is recommended that signed documentation of the training be available for verification.

In a large vaccination clinic, an initial question session may be provided by personnel who are versed in interview techniques (disease investigators, for example). Persons may be referred to medical screeners based on their answers to the questionnaire.

Medical Screeners should rehearse the medical screening session to estimate the time that it will take to conduct the screening. The medical screeners will complete the following activities:

- Ask if the vaccinee has any questions related to the VIS.
- For individuals returning for second vaccination dose, review medical history since first dose including any problems with first dose.
- Ensure accuracy of tier group assignment, documentation and entry.
- Document and assure that all potential vaccinee questions are answered.
- Review contraindications to vaccination and record on MIP approved forms.
- Review common reactions and possible serious adverse events to the vaccine.
- Explain common, typical, or mild reactions.
- Answer questions/concerns regarding Influenza.
- Obtain consent form.
- Refer potential vaccinee to the vaccination station (VS).

It is paramount that medical screeners take the utmost care to ensure that potential vaccinees have been screened and understand risks and benefits of vaccination.

F. Vaccine Administration Station

Vaccine will be administered according to the recommendations of the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) recommendations.

Medically-trained personnel who are authorized to administer vaccinations under state law can administer influenza vaccine

The MIP is responsible for data collection, entry and record maintenance for this vaccination program even if the vaccine is administered by trained staff outside the MIP. The MIP will ensure that no later than close of business the next day and preferably the day of vaccination, all appropriate vaccination information will be entered into Impact 2 or a designated paper system. All client forms that contain confidential medical information should be managed as confidential data, following applicable departmental policy and protocol for ensuring data confidentiality.

Once the data is entered into IMMPACT 2 or via paper system, the vaccine doses will be deducted from the existing influenza vaccine inventory. In addition, the vaccine utilization report will reflect updated doses administered.

Aggregate statewide vaccination data will be reported from MIP to the CDC's Countermeasure Response Administration (CRA) System weekly. Weekly reporting will be required by noon Monday of each week following the MMWR reporting schedule.

G. Exit Review

The Exit Review by a medical health care professional at the exit station will include the following activities:

- Collection of a signed consent form.
- Review side effects with vaccinee using the Vaccine Information Sheet; Reactions after Vaccination information sheet.
- Provide vaccinee an emergency 24/7 contact number.
- Answer remaining questions or concerns regarding influenza vaccination.
- Complete consent to release medical information to the employer if indicated.
- Schedule appointment or remind vaccinee of the due date for the subsequent vaccination if first visit.

The MIP will maintain the completed consent form in accordance with the current Maine DHHHS *policies.*

Supplement F. Adverse Event Medical Management

The Maine CDC will support the medical and epidemiologic management of vaccinees presenting with adverse events by: (1) providing vaccinee and provider appropriate education and information, (2) facilitating triage and referral to healthcare providers for severe adverse events as requested, (3) identifying regional hospital-based physicians who are willing to see vaccinees with clinically-significant adverse events.

Vaccinees experiencing adverse events are likely to present to their primary care physician, or an emergency room. The Maine CDC must have a process in place to support medical management regardless of where or how a vaccinee presents with adverse events.

The medical management of adverse events associated with receiving the Influenza vaccine will be accomplished through the established healthcare system.

- The Division of Disease Control will identify the State Vaccine Adverse Event Reporting System (VAERS) Coordinator for reporting of adverse events.
- The Division of Disease Control will conduct ongoing epidemiologic analysis of adverse events in Maine.

B. U.S. CDC Responsibilities

- Provide 24/7-coverage for clinical guidance.
- Provide 24/7-coverage for State Health Department technical assistance.
- Monitor clinically-significant adverse events at the national level.
- Monitor reported adverse events for the occurrence of unexpected adverse events.
- Provide clinical consultation line for providers for information about adverse events and who should be notified should adverse events occur.
- Conduct epidemiologic studies to identify risk factors for adverse events following Influenza vaccine.
- Conduct epidemiologic studies to evaluate causality of unexpected adverse events.

C. Adverse Event Reporting

- Surveillance for Adverse Events: Maine CDC will conduct surveillance for potential serious adverse events. Each vaccine will be provided with a 24/7 number to call if they are experiencing an adverse event.
- Reporting of all Adverse Events: The VAERS reporting process reflects the VAERS reporting process that is done for all vaccines. Clinic staff is responsible for initiating the VAERS report when an adverse event is suspected or occurs.

Note: Not all reactions that occur during the vaccination sequence are unexpected and/or characterized as adverse events. Events that meet the case definition for influenza adverse events, anaphylaxis, serious illnesses and/or hospitalizations following influenza vaccination should be reported.

Additional guidance for determining unexpected reactions that are adverse events will be provided as it becomes available.

- Submit reports of adverse events to the State Vaccine Adverse Event Reporting Coordinator by faxing the VAERS form to MIP as soon as possible.
- The VAERS Form, assistance in completing the form, or answers to other questions about VAERS are available via a 24-hour toll-free telephone number: 1-800-822-7967**.** The reporting form can be downloaded from the VAERS web page at www.vaers.hhs.gov.
- Immediately after faxing the VAERS form to the State VAERS Coordinator, fax the report to the National VAERS Program at 1-877-721-0366.
- VAERS Reports may also be submitted electronically to VAERS, but only after printing out and faxing a copy to the MIP for electronic submission in addition to the VAERS Web Submission link can be accessed at the following Internet site: www.vaers.hhs.gov.
- Attach pertinent information from the vaccines' medical record for serious adverse events.
- Submission of a VAERS report
    - Enter data regarding adverse events into the VAERS Form as soon as possible.
    - Incomplete reports should be submitted with as much information as soon as possible to ensure Maine CDC and National VAERS staffs have all available information on potential adverse events.
    - The vaccine provider or primary care physician will send all reports to the MIP and the National VAERS office as they occur. Do not send batches of reports. Do not wait for complete documentation before sending to VAERS, especially if the report appears serious. VAERS data is reviewed on a daily basis so that analysis and follow-up of serious reports can be conducted. Timely reporting is essential for timely follow-up investigation, especially if clinical specimens may need to be obtained.
    - The National VAERS office will send a confirmation notice to the reporter for all reports received, whether mailed or faxed. A unique VAERS ID number will be provided with the confirmation notice. Any follow up correspondence about a report must include the VAERS ID number. Reports are entered into the VAERS database under a unique ID number. It is also helpful to have the patient's name and date of birth, if available, to help identify the specific report.
    - Information such as medical records or autopsy reports may be submitted to National VAERS by phone, mail or fax. All copies must also be submitted to the Maine CDC, Maine Immunization Program at the time you submit them to the National VAERS program.

Supplement G: Vaccine Safety

A. Clinical and Ethical Safeguards

Monitoring and safety procedures for potential adverse events are assigned for each vaccine provider and an adverse event reporting system is in place.

Vaccination is **voluntary** for all designated priority group members.
Informed consent is a precondition for participation.
Eligibility criteria are developed based on impact of the disease on population groups.
Priority in selection of participants will be based on federal guidance.
At the vaccination clinic itself, **pre-vaccination screening** for contraindications should be conducted, the provision of risk/benefit information should be provided, and the patient's informed consent obtained. This evaluation and pre-requisites for vaccination should be conducted by trained personnel.
Claim or suit arising out of the administration of the vaccine must be filed solely against the Federal Government.
Monitoring and safety procedures for **dealing with potential adverse events** are assigned for district and an adverse event reporting and referral system is in place, right through to CDC.

Supplement H: Communications

A. Communications Flow, Support and Management

- Partnership: Establishing District-Level influenza "Points of Contact"
  The Vaccine Coordinators will be responsible for communication within their jurisdiction to healthcare providers and the public.
- Issue Resolution: Issues raised will be reviewed through the Maine CDC Communications Officer, Tara Thomas, when necessary and a response given as soon as possible, or at the latest within 48 hours. Issues should be sent by email to: Tara.thomas@maine.gov.
- Regular briefings between the Influenza Mass Vaccination Implementation Team, the Regional Resource Centers, and Vaccine Coordinators will underpin the partnership. Regularly scheduled conference calls with the Maine CDC planning team (DL,VC, RRCs) will be made available.

B. Communications Tracks

There are two main audiences in this communications process – designated priority group members and general public.

The Maine CDC will continue to update and improve a repository of assets and knowledge on the circulating influenza will be made available on the Maine CDC website at: http://wwwmainepublichealth.gov .

A more detailed listing of the contents of the influenza communications assets will be provided as they become available.

Directly, participants are informed individually and through professional affiliation or employment channels. Special needs are met with targeted information, largely derived from CDC source materials. The Maine CDC will work in conjunction with the Influenza Mass Vaccination workgroup to handle this task in direct collaboration with the DLs, VCs, RRCs.

Supplement I. Reporting and Data Management

Vaccine inventory, doses administered, contraindications, adverse events and tier group assignment will be completed using the CRA reporting form. Doses administered will be entered preferably the day of vaccination but no later than by close of business the day following vaccine administration. There are three possible scenarios for reporting:

- Vaccine Coordinators (or clinics) enter data directly onto the U.S. CDC vaccine card for Maine CDC-hosted clinics (vaccine cards will be shipped with vaccine and ancillary supplies).
- Private providers provide vaccination data on all vaccinations provided in their facilities to MIP in accordance with required reporting timeframes.

Statewide aggregate data will be uploaded from MIP to the Centers for Disease Control and Prevention Countermeasure Response Administration System weekly by the following Monday of each week. This reporting periodicity is required in order to meet MMWR publication deadlines.

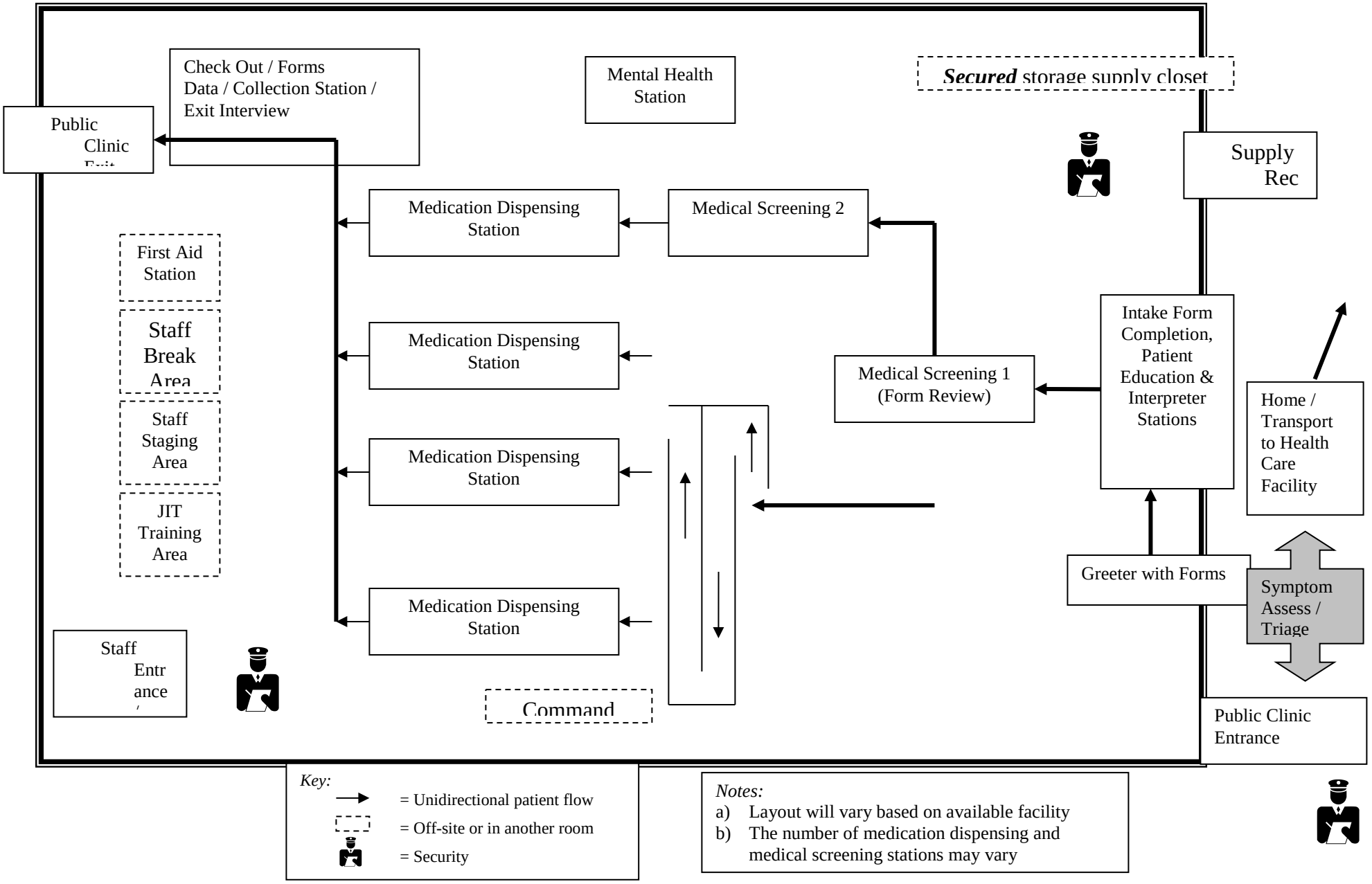
A. Immunization Registry

For detailed information on how to enter Influenza data into the immunization module, please contact MIP at: 1-207-287-2541.

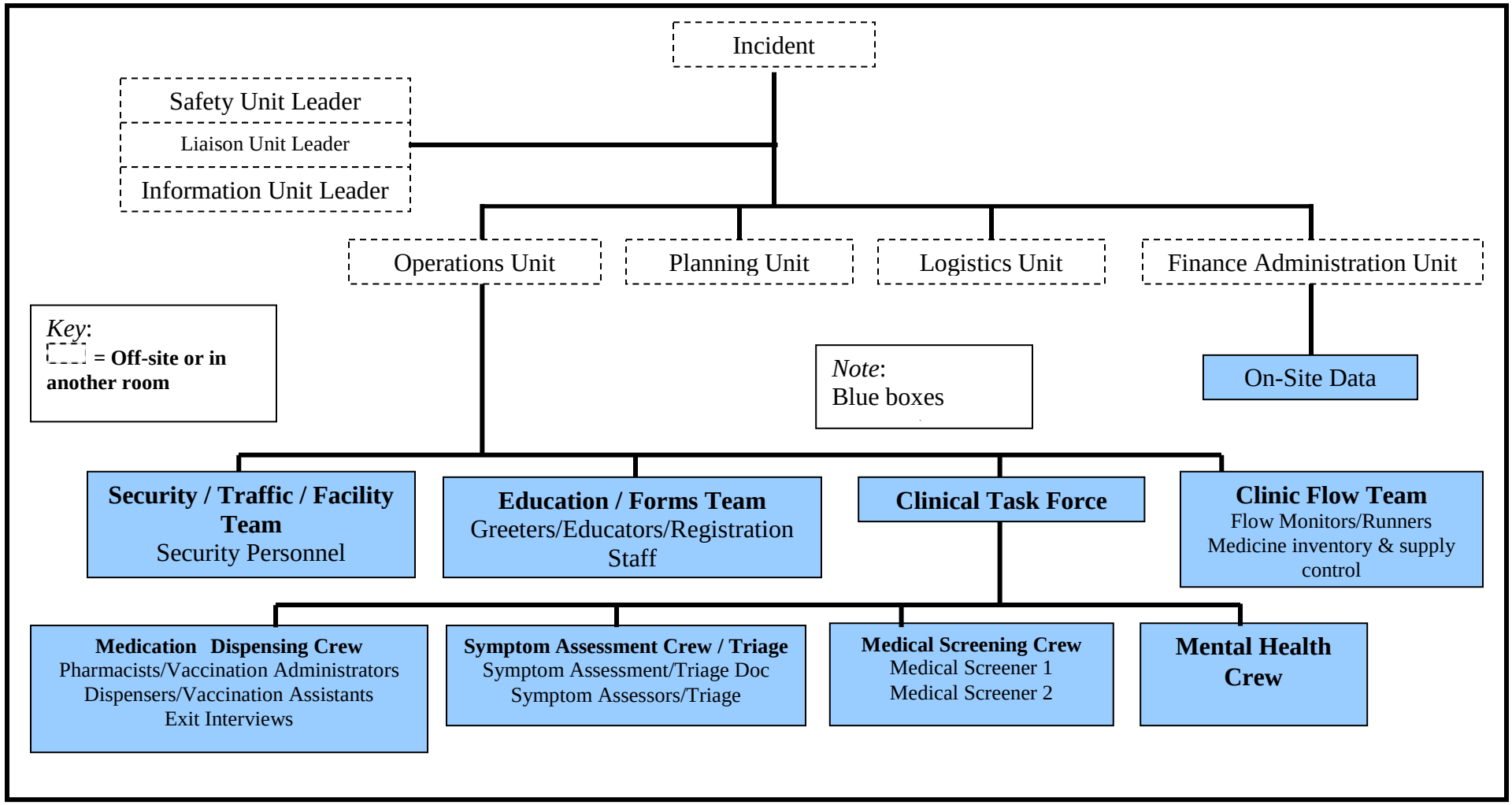
C. Reports

Reports to be determined.

Supplement J. a. Mass Vaccination Clinic Floor Plan



Supplement J. b. Mass Vaccination Clinic Organizational Chart
Maine 2007



Supplement J.c. Instructions for Patient Flow through Mass Vaccination Clinic

Triage/Symptom Assessment

- Identify symptomatic patients and direct them to a hospital or designated medical care facility for treatment
- Direct healthy patients to enter the clinic.

Forms Distribution/Education Area

- Provide information about what is currently known about the disease, people who may have been exposed, purpose of medication and distribution process, and nature of recommended medication.
- Provide information on contraindications and direction on how to complete Medical Screening Form.
- Answer questions.
- For vaccination, review forms for accuracy and completion.

Medical Screening 1 (Form Review)

- Review Medical Screening form.
- If **NO** to all questions, direct patients to medication teams.
- If **YES** to any question, direct patients to Medical Screening 2 for more in-depth screening
- Weigh as needed.

Medical Screening 2

- Review Medical Screening form.
- Identify contraindications and obtain necessary health history information.
- Provide medical information, answer questions, and assure appropriate prescriptions provided if needed.
- If patients clear screening, direct to medication dispensing station.
- If patients do not clear screening, direct to Clinic Exit, or refer to hospital or designated medical care facility as appropriate.

Medication Dispensing Station

- Verify patient's Medical Screening Form.
- Provide medication.
- Educate patient on post-care instruction. Validate understanding of post-care instructions.
- Document necessary information and collect Medical Screening form (if Check Out station not established).
- Refer patient to Mental Health if necessary.

Mental Health

- Counsel patients and answer questions.
- Document visit.
- Redirect patient into clinic flow or to Clinic Exit as appropriate.

Check Out (if established)

- Collect Medical Screening Form
- Exit Interview

APPENDIX

Appendix 1
U.S. CDC Vaccination Campaign Planning Checklist

Introduction:	This document is intended for state and local planners. Its purpose is to outline the main influenza vaccine planning actions. It is not meant to be exhaustive, and more detailed guidance is, or will be, available on specific topics. Within each state, the checklist should be tailored to distinguish between state and local responsibilities.	
General:	☐	Ensure clear delineation of responsibilities and establish regular communication between involved programs at state level (Preparedness, Immunization, others)
	☐	Establish clear delineation of responsibilities and regular communication channels between state and local programs
Target and Priority Groups:	☐	Determine estimated size in jurisdiction of target and priority groups as defined by ACIP.
	☐	Develop plans which may include public health sponsored clinics or vaccination via private sector vaccinators to reach each target and priority group.
Public Health Vaccination Clinics:		**(clinics that are conducted, organized or sponsored by public health)**
	☐	Determine populations that will be targeted for vaccination via large scale/public health sponsored clinics
	☐	Identify clinic sites (number, locations, points of contact, alternative sites, accessibility)
	☐	Estimate size and type (target and priority groups) of population to be served per site
	☐	Determine staffing needs, and sources of staffing
	☐	Develop plans for staffing, including identification of sources of volunteers and development of MOAs with relevant organizations.
	☐	Initiate contracts with personnel agencies or community vaccinators to provide staff or organize/conduct clinic
	☐	Define process to allow healthcare workers from other jurisdictions to vaccinate if necessary

Vaccination by Private Sector Vaccinators:	☐	Meet with and disseminate information through medical societies, hospital associations, healthcare provider professional organizations
	☐	Conduct mail outs or blast fax information to lists of providers obtained from licensing boards or medical societies or using existing tools for communicating with providers (e.g., HAN messages or state public health bulletins)
	☐	Identify clinical providers and health systems interested in administering vaccine (e.g. pediatricians, including non-VFC providers, family physicians, Obstetrician/Gynecologists, internists, HMOs, hospitals and other health care facilities)
	☐	Identify commercial community vaccinators (e.g. retail based clinics, medical services firms, urgent care center) interested in administering vaccine
	☐	Develop a pre-registration process so vaccinators can indicate interest, receive information updates as available, and provide information needed for vaccine delivery
	☐	Provide easily-locatable information on health department web site for vaccinators, indicating what role they might play in given state/jurisdiction and how they can obtain information
	☐	Use federal language, once available, to develop provider agreement between providers and public health
	☐	Contact large businesses regarding plans for worksite vaccinations
	☐	Contact college and university health centers
Coordination with Other Partners:	Collaborate with the following systems and facilities, where applicable, as above to ensure vaccination of populations served or associated with them:	
	☐	Military bases to develop plan for military dependents
	☐	VA clinics
	☐	IHS clinics and tribal clinics
	☐	FQHCs and RHCs (including reaching out to state Primary Care office and Primary Care Association)
Coordination of Vaccine Distribution:	☐	Determine overall relative allocations for public health clinics, including school-located vaccination, clinical providers, and other private sector providers (e.g. community immunizers, retail providers).
	☐	As part of pre-registration or registration process, collect number of influenza doses administered previous year, where applicable, to help determine provider capacity for administering influenza vaccine.

	☐	Where jurisdictions cross state lines, coordinate vaccine allocations across states.
	☐	Determine plan for allocating vaccine (e.g. partial shipments to all providers, sequential shipments to sets of providers).
	☐	Develop staffing plan for entry of data into VACMAN (application utilized by immunization program grantees).
	☐	Develop plan for provider practices unable to accommodate minimum shipment size (internal distribution, limiting vaccine to larger sites).
	☐	Develop plan for tracking vaccine usage by vaccinators to ensure vaccine supply is adequately directed where needed.
Vaccination of Healthcare Workers and EMS Personnel:	☐	Develop agreements with hospitals to delegate responsibility for vaccination of staff, and determine size of staff (total and staff with direct patient contact).
	☐	Collect required information (e.g. shipping address, contact persons, etc.) for vaccine delivery.
	☐	Develop plan for outpatient providers (e.g. they may receive vaccine directly through centralized distribution, or if not among the first to receive vaccine may pick up at defined location).
	☐	Develop plan for vaccinating EMS personnel.
Vaccination of School-aged Children:	☐	Make connections with education partners at state level.
	☐	Make connections with education partners, including school districts, at local level; create a list of schools/school districts willing to participate in school-located clinics.
	☐	Develop plans for staffing school-located clinics, including identification of sources of volunteers and development of MOAs with relevant organizations.
	☐	Develop informational materials for parents.
	☐	Work with local legal advisors to design consent forms.
	☐	Develop plans to distribute and maximize return of consent forms where applicable (i.e., if school clinics during school hours and without parents present are planned).

	☐	Ensure VIS is provided to parents for each vaccination dose.
	☐	Develop plan to inform and obtain support of principals, teachers and parent organizations.
	☐	Develop plan for informing and obtaining support from physicians in the community about school-located vaccination.
Hard to Reach and Vulnerable Populations:	☐	Define hard to reach populations.
	☐	Estimate size of populations.
	☐	Develop plan for reaching these populations and/or transporting to clinic sites.
	☐	Develop MOAs with public agencies, volunteer organizations, and others to reach these populations.
Tribal Populations:	☐	Include IHS and tribal planners in developing and finalizing vaccinations plans.
	☐	Ensure tribal populations are included in state vaccine allocation plans.
Communications:	☐	Ensure clear communication about implementation of target and priority group recommendations and need for second dose.
	☐	Develop targeted (to recommended groups) messages to advertise vaccination clinics and vaccinators participating in vaccination program.
	☐	Involve local stakeholders and/or key audience liaisons in shaping outreach strategies.
	☐	Identify language and cultural barriers and plan for addressing.
	☐	Plan testing of messages for receptivity, understanding.
	☐	Create MOAs with channels for communication (e.g., community and social or religious networks, commerce or local business partners).
	☐	Determine best means for targeting communication broadly to different ethnic and socioeconomic populations (e.g., media, clinician outreach, websites or new media).
	☐	Reach out to widely diverse local partners, volunteer groups and other NGOs with specific instructions and technical support on how to help disseminate messages and aid the general public in accessing vaccination sites.

	☐	Plan information communication network throughout agencies at state and local levels to ensure coordination of messages.
	☐	Conduct ongoing assessment of strategies, and adjust messages as needed.
Large-scale Clinic Planning:		
	General:	
	☐	Determine cold storage capacity for vaccine at site
	☐	Determine status of communications equipment
	☐	Develop procedure for receiving and accounting for vaccine
	☐	Develop site layout, patient flow, job descriptions, equipment needs
	☐	Develop plan to provide ID to clinic staff
	☐	Develop plan for responding to medical emergencies or adverse events (e.g. fainting)
	☐	Develop plan for data collection
	☐	Develop process for vaccination of non-English speakers (identify language needs and needed staffing)
	☐	Ensure information on return date for second dose is provided
	☐	Contact information for staff updated and available
	☐	Develop training materials including just-in-time training plan
	☐	Develop contingency plans in the event of staff absenteeism
	☐	Develop plan for advertising clinics to public and potential vaccinators
	School-located Clinics:	
	☐	Address issues specific to vaccination of children (flow from classroom to vaccination)
	☐	Plan for consent related issues at time of clinic (verifying identity of consented child when parent is not present)

Doses Administered Tracking:	☐	Determine data collection system and method for reporting minimum required data elements
	☐	Define local data collection needs
	☐	Distribute educational materials to vaccine administration sites
	☐	Develop staffing plan and training for data collection, entering and forwarding at public clinics and at local and state health departments
	☐	Determine equipment needs at all data collection and forwarding sites
Safety Monitoring:	☐	Identify and implement mechanisms to communicate vaccine safety information on a routine and urgent basis with vaccine providers
	☐	Disseminate information to vaccinators to increase awareness of VAERS reporting
	☐	Develop a plan to respond to vaccine safety concerns from providers and patients at the state and local level
	☐	Identify staff that could assist in the event of a field investigation of adverse events following immunization
	☐	Communicate to vaccine providers the availability of CDC provided vaccination cards with date of vaccination, 1st dose/2nd dose, lot number, return date for 2nd dose, VAERS information
Legal:	☐	Contact primary public health counsel to determine which allied health professionals are legally permitted to administer vaccine, to what types of patients, and under what conditions.
	☐	Ensure dissemination/explanation of PREP Act information to planners and vaccinators
For state and local jurisdictions where at least some vaccine will be shipped to a central receiving site and repackaged for shipping to other sites/providers:		
General:	☐	Develop system to track inventory from receiving site to further points of distribution to be able to replenish supply in timely manner
Vaccine Receiving Sites:	☐	Define staff responsibilities with respect to vaccine administration

	☐	Calculate staff needs for receiving, storing, breakdown, repackaging (taking into account absenteeism)
	☐	Develop training materials
Storage and Handling:	☐	Ensure adequate storage space for both refrigerated (preloaded syringes and multi-dose vials of vaccine and possibly, adjuvant) and non-refrigerated supplies
	☐	Ensure adequate supplies to maintain cold chain during storage and transportation of vaccine at both the storage and vaccination clinics
Transportation:	☐	Plan for transporting vaccine from receiving site to distribution sites
	☐	Review and, if necessary, revise, contingency plan for transportation
	☐	Identify source and number of transportation staff needed (taking into account absenteeism)
	☐	Develop training materials
Security:	☐	Provide security at receiving sites, in transport to administration sites, and at administration site
	☐	Have contingency plan in place for unexpected disruptions at administration site(s)
	☐	Identify staffing for security
	☐	Develop training materials

Appendix 2
Influenza Vaccination Clinic
Sign-Up Sheet

Clinic Date: _____ Clinic Location: _____

Each worksite Flu Shot Clinic will be staffed by at least two Public Health Nurses. Clinics will begin at 9 AM, unless arrangements have been otherwise made with the Regional Public Health Nursing Supervisor. The clinic's end time will depend upon the regular worksite hours. Approximately 40 employees can be given shots each hour. Please fill in the time slots beginning with the first hour and continue filling in the hourly time slots until all the morning slots are filled, before you begin using any afternoon time slots.

9:00 AM – 10:00 AM

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10:00 AM – 11:00 AM

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11:00 AM – 12:00 (Noon) **Date _____ Location _____**

1:00 PM – 2:00 PM

2:00 PM – 3:00 PM **Date _____ Location _____**

3:00 PM – 4:00 PM

4:00 PM – 4:30 PM (Last shot at 4:30 P.M.; Clinic ends at 5:00 PM

Appendix 3
Department of Health & Human Services
Maine Center for Disease Control and Prevention

Employee Influenza Vaccine Clinic

NAME: _____ BIRTHDATE: _____ AGE:_____
First Middle Last

ADDRESS: _____
Street or Box # City Zip

TELEPHONE: _____ _____
Home Phone Work phone

PRIMARY HEALTH CARE PROVIDER: _____

EMPLOYEE HEALTH SCREEN

1. Are you well today?	☐ Yes	☐ No
If no: Do you have a fever?	☐ Yes	☐ No
2. Do you have any allergies? If yes, what_____ _____	☐ Yes	☐ No
3. Do you have an allergy to egg protein or chickens?	☐ Yes	☐ No
4. Are you sensitive to Thimerosal, a preservative used in vaccines?	☐ Yes	☐ No
5. Are you sensitive to dry natural latex rubber?	☐ Yes	☐ No
6. Have you ever had a serious allergic reaction or other problems after getting an Influenza Vaccine?	☐ Yes	☐No
7. Do you have a history of Guillain-Barre Syndrome?	☐ Yes	☐ No
8. Do you have an active neurological disorder?	☐ Yes	☐ No
9. Do you have a bleeding disorder (hemophilia or thrombocytopenia) or are you on anticoagulant therapy?	☐ Yes	☐ No
10. Are you Pregnant?	☐ Yes	☐ No

I have read the vaccine information statement and have had a chance to ask questions that were answered to my satisfaction. I understand the risks and benefits of the influenza vaccine. **I understand that I will be asked to stay 15 minutes after I receive my flu shot.** I ask that the influenza vaccine be given to me.

Signature:_____ Date:_____
Person to receive vaccine

Date Given	Manufacturer	Lot #	Site	Dosage	Provider Signature
	Sanofi-pasteur ☐ ☐		RD LD	0.5cc IM	

Appendix 4
Department of Health & Human Services
Maine Center for Disease Control and Prevention

Record of Transportation of Vaccines/Biologicals to a Facility for Emergency Cold Storage

Name of Facility _____ **Location** _____

Date & # Doses Dropped Off	Time Dropped Off	Nurse's Signature	Date & Doses Returned	Time Returned	Nurse's Signature	Name Of Vaccine/ Biological	Lot #s	Manufacturer	Comment

Appendix 5
Department of Health and Human Services
Maine Center for Disease Control and Prevention

Record of Temperatures During Transport of Vaccine to an Immunization Clinic

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 PHN 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^o - 46^o F)	Out of Range < 35^o F OR > 46^o F	Action Taken	Signature
Arrival at clinic site TIME:					