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PLANNING GUIDE FOR VACCINATING PEDIATRIC PATIENTS AGAINST H1N1 INFLUENZA IN PRIVATE HEALTHCARE SETTINGS

Purpose of this document: To provide guidance for planning and conducting 2009 H1N1 Influenza vaccination of pediatric patients in private healthcare settings.

Target Audience: Physicians, nurses, office planners, infection control coordinators and anyone responsible for carrying out 2009 H1N1 influenza vaccination in private healthcare settings. This document is also intended for state and local public health planners to help them be aware of the considerations needed for private healthcare providers to distribute H1N1 vaccine and to assist in coordinating the overall community H1N1 response.

Glossary:

- AAP: American Academy of Pediatrics
- ACIP: Advisory Committee on Immunization Practices
- CDC: Centers for Disease Control and Prevention
- COOP: Continuity of Operations Planning
- CRA: Countermeasure and Response Administration
- EMAC: Emergency Management Assistance Compact
- ESAR-VHP: Emergency System for the Advanced Registration of Volunteer Health Professionals
- FDA: Food and Drug Administration
- HHS: Health and Human Services
- ICS: Incident Command System
- IIS: Immunization Information System
- MRC: Medical Reserve Corps
- PCMH: Patient-Centered Medical Home
- PREP Act: Public Readiness and Emergency Preparedness Act
- RBC: Retail-based clinic
- UCC: Urgent care clinic
- VAERS: Vaccine Adverse Event Reporting System
- VIS: Vaccine Information Statement

Definitions:

Private Healthcare Located Vaccination is administered in private healthcare settings including:

- Private provider offices (pediatricians, family practice physicians, primary care providers, obstetricians/gynecologists)
- Federally Qualified Health Centers, Urgent Care Clinics, Retail-based clinics
- Hospitals
- Long-term care facilities

Background:

The first available doses of the 2009 H1N1 influenza vaccine are anticipated by mid-October. CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that the following groups first receive the H1N1 vaccine when it becomes available

(<http://www.cdc.gov/h1n1flu/vaccination/acip.htm>):

- **Pregnant women** because they are at higher risk of influenza-related complications and can potentially provide protection to infants who cannot be vaccinated;
- **Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants less than 6 months old might help protect infants by "cocooning" them from the virus;
- **Healthcare and emergency medical services personnel** because infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;
- **All people from 6 months through 24 years of age**
 - **Children from 6 months through 18 years of age** because we have seen many cases of novel H1N1 influenza in children and they are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and
 - **Young adults 19 through 24 years of age** because we have seen many cases of novel H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and,
- **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

The priority age groups include pediatric patients 6 months through 18 years of age, a group that is also recommended to receive the annual seasonal influenza vaccine (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0724a1.htm>). As state and local planners determine the vaccine planning actions needed in their community (http://www.cdc.gov/H1N1flu/vaccination/statelocal/planning_checklist.htm), they should consider private healthcare sector vaccinators as a key partner in an overall tiered approach.

There are several benefits to vaccinating children in private healthcare settings:

- Vaccinating in private healthcare settings allows children to remain in the care of their medical home (<http://www.medicalhomeinfo.org/Joint%20Statement.pdf>) - this ensures comprehensive care and easy access and tracking of children's medical records.
- Private physicians have established relationships with families of children requiring vaccination – parents are used to seeking care and advice from their family physician or pediatrician and trust these individuals to treat their children.
- Children regularly visit private healthcare entities for care – this gives an opportunity to combine vaccination with health supervision visits, acute, trauma and chronic visits (e.g., asthma or diabetes visits) and to vaccinate others who may accompany a child to their appointment (siblings, pregnant mothers).
- Private healthcare providers possess the experience and clinical expertise to monitor, respond to, and report any adverse events associated with the H1N1 influenza vaccine.
- Private healthcare settings are familiar with the billing and recording procedures that accompany typical vaccine distribution; therefore, vaccination in these settings may be more efficient.
- Private healthcare settings are more likely to be able to vaccinate children ages 6 months to 4 years that might be missed because they are not in school.

There are also several potential challenges with providing H1N1 vaccines in private healthcare settings:

- Providing H1N1 vaccine and seasonal influenza vaccine - while treating potentially large numbers of ill and infected children- could potentially be a large source of surge and may be overwhelming to staff. Providing H1N1 vaccine may not be a feasible option for all private healthcare facilities depending on size, available resources, and capabilities.
- Many private healthcare entities lack the clinical space required for H1N1 vaccination.
- Vaccinating in private pediatric offices mixes large numbers of ill (or exposed) children with well children waiting to be vaccinated. Vaccinating children in general practice

settings potentially exposes adult/geriatric patients groups that are not a priority for vaccinating to the H1N1 virus.

- Some providers may not have the cold-storage capacity to appropriately refrigerate H1N1 vaccine in addition to seasonal influenza vaccine. Purchasing additional refrigerators for storage can be costly.
- Vaccines could present a financial burden to private healthcare facilities. The federal government is providing vaccine and supplies to providers at no charge and providers are allowed to charge an administration fee. However, all insurance companies may not reimburse this fee to an extent that will cover extra costs associated with taking on the responsibility of offering an extra service during what is typically an already busy season (e.g., overtime expenses for staff).
- In some areas, private healthcare providers have not been sufficiently integrated into community emergency planning activities. Therefore, private healthcare entities often lack basic knowledge of preparedness planning principles (e.g. Incident Command System (ICS), Continuity of Operations Planning (COOP)).
- Private healthcare providers often vaccinate all patients requesting vaccination in their office. In cases where vaccine supply is temporarily limited and available only for select high-risk populations, it may be difficult for healthcare providers to deviate from their normal practice standards to follow recommended protocols.

Vaccine Implementation in Private Healthcare Settings: “Just in time” Planning Checklist

Initial Planning: Determine if your facility will provide H1N1 Vaccine		
<p>What Plans are in Place? How do I fit in?</p> <p>(Step 1)</p>	<p>Familiarize yourself with the requirements in your state’s provider agreement (see additional information and resources section below).</p> <p>Find out your state and local public health agencies’ plans for H1N1 vaccinations in your community.</p> <p>For example:</p> <ul style="list-style-type: none"> • Do they have a plan for private providers to be vaccine providers? • Do they plan to use mass vaccination clinics to reach the public? <p>Consider having a planning meeting with all stakeholders (e.g. other private providers, public health, emergency management agencies, etc.) to formulate a plan. Integrate to receive input from all areas before making a decision.</p> <p>Familiarize yourself with liability and legal protections for providers and additional staff giving vaccines:</p> <p>http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html.</p> <p>For more information on Public Readiness and Emergency Preparedness (PREP) Act Declarations:</p> <p>http://www.hhs.gov/disasters/discussion/planners/prepact.</p>	
<p>Additional Information and Resources</p>	<p>Each state or jurisdiction will have its own provider agreement. See the <i>State/Jurisdictional Contact Information for Providers Wanting to Give H1N1 Vaccine</i>:</p> <p>(http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm).</p> <p>If you do not find a contact or link to your state’s provider agreement through the above link, go to your state department of health website.</p>	
<p>(Step 2)</p>	<p>Talk to other providers (hospitals and offices/clinics) to see what options they are considering for their patients.</p>	

Needs Assessment	<p>Write down a list of who in your practice or facility would need to receive H1N1 vaccine.</p> <p>For example:</p> <ul style="list-style-type: none"> • Healthcare workers and staff • Volunteers who may not meet the prioritization requirements • Patients that need vaccine based on current ACIP guidance • Patients that usually get their vaccines from your practice 	
How do we finance this and what is required to recoup costs?	<p>The H1N1 vaccine will be distributed to providers free of charge and will include needles, syringes, sharps containers and alcohol swabs. Providers will be able to charge a fee for vaccine administration.</p> <p>Look into billing/reimbursement issues and clarify what the policies will be for your office should you participate.</p> <p>Estimate potential costs for additional supply and staffing costs associated with administering the H1N1 vaccine.</p>	
Additional Information and Resources	<p>[Recommendations and Resources provided by AAP will be inserted here]</p>	
What are our major staffing needs? (Step 1)	<p>Make a determination of what kind of staffing complement you may need to see your patients for H1N1 vaccination.</p>	
Additional Information and Resources	<p>Refer to the <i>CDC Guidelines for Large-Scale Influenza Vaccination Clinic Planning</i> (http://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm).</p> <p>Consider that you may need to have staff who perform the following functions in excess of normal routine business:</p> <ul style="list-style-type: none"> • Triage or initial intake (screening) – To determine which patients fall into the priority groups for H1N1 vaccination and those that will not receive vaccine • Managing room/space and patient flow – this may include 	

	<p>runners to keep vaccinators and assistants supplied</p> <ul style="list-style-type: none"> • Vaccinating patients and monitoring for adverse reactions • Billing/Administrative paperwork • Immunization Registry data entry – this role could be filled by volunteers (consider contacting your local health department for assistance if you cannot find volunteers within your practice. Some health departments are offering to assist providers with entry into immunization registries). <p>Depending on the size of your practice and the demand for vaccine from patients, your clinic may need to scale down or modify the <i>High-Volume Influenza Vaccination Clinic diagram</i> provided in the above guidance.</p>	
(Step 2)	Consider the legalities of the type of staff you may use (students, volunteers, retirees).	
Additional Information and Resources	Ask the state chapters of your medical societies about laws regarding who legally can give vaccines and/or if there are training programs for those wishing to help vaccinate.	
What is my storage capacity?	<p>Determine how much space you have to store the H1N1 vaccine in addition to your current vaccine inventory.</p> <p>H1N1 vaccine will need to be maintained at 2-8°C (35°F and 46°F) and will be available in single dose syringes and multi-dose vials. Vaccine will be available in lots of 100 doses.</p>	
Additional Information and Resources	<p>Contact your emergency management agency, public health department and/or local hospital for the possibility of shared community storage.</p> <p>For more information on vaccine storage and handling go to:</p> <p>http://www.cdc.gov/vaccines/recs/storage/default.htm</p> <p>http://www.immunize.org/catg.d/p3035.pdf</p>	
<p>Identify the potential problems you may face if you choose to offer H1N1 vaccines, and then see if your community contacts can help you address those problems.</p> <p>Make a decision about whether to continue forward with your H1N1 vaccine planning.</p> <p>If you are unable to provide H1N1 vaccine, familiarize your practice with the community vaccine</p>		

distribution plan and develop appropriate messaging to give to parents that call or show up in the office wanting a vaccine.

Consider volunteering in school-based or other large- scale community vaccine distribution clinics.

Moving Forward: Planning to provide H1N1 vaccine to your patients and/or the community

Placing your orders	<p>Estimate the number of vaccine doses you may need based the amount of seasonal flu vaccines you have administered in previous years. Refer back to your needs assessment list above.</p> <p>Take necessary steps to order vaccine supply through your public health agency by completing a provider agreement.</p> <p>Note- Vaccines will be distributed in sets of 100 doses.</p>	
Additional Information and Resources	<p>Consult state and local public health officials to obtain a copy of your state's provider agreement form/survey:</p> <p>(http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm)</p>	
Storage and capacity to store	<p>Determine your current inventory for vaccine and space requirements for additional vaccine and formulate a vaccine-handling and storage plan.</p>	
Additional Information and Resources	<p>H1N1 vaccine will need to be maintained at 2-8°C (35°F - 46°F).</p> <p>Talk with your emergency manager or hospital to consider different methods of refrigeration:</p> <ul style="list-style-type: none"> • Portable refrigerators with thermometers • Sharing refrigerator space with others • Storing at one central location (hospital) <p>Coordinate with public health agencies to provide vaccine to your practice in increments dependent on your capacity (e.g. weekly shipments to avoid overrunning refrigeration space).</p>	
Billing/ Reimbursement	<p>The HCPC codes for the H1N1 vaccine are as follows:</p> <ul style="list-style-type: none"> • G9141 – Influenza A (H1N1) immunization administration (includes the physician counseling the patient/family) • G9142 – Influenza A (H1N1) vaccine, any route of administration <p>Think through various payment options. Consider cash-only options</p>	

	and separating billing for office visits from vaccine visits.	
Additional Information and Resources	<p>For more information on Billing for the Administration of the Influenza A (H1N1) Virus Vaccine: http://www.cms.hhs.gov/MLNMattersArticles/downloads/se0920.pdf</p> <p>[Recommendations and Resources provided by AAP will be inserted here]</p>	
Human Resources (HR)/Staff planning	<p>Talk to your Human Resources (HR) person about overtime policies and other potential problems that might arise.</p> <p>Consider situations where staff may refuse vaccine or become ill.</p> <p>Review or create appropriate HR policies.</p>	
Develop your plan and get feedback (Step 1)	<p>Decide/discuss when vaccines will be given in your office (e.g., regular hours, special shifts, weekend clinics).</p> <p>It will be critical to obtain staff buy-in to any altered scheduling.</p>	
Additional Information and Resources	<p>Options to consider:</p> <ul style="list-style-type: none"> • Extend hours to hold early morning and evening vaccine clinics. • Consider weekend clinics. • Partner with others (particularly for small practice settings) to share the burden of extended staff hours. • Vaccinate all children that enter the office – including those that accompany siblings on well-child, acute, or chronic visits. • Temporarily suspend well-child visits and other non-essential activities to accommodate surge of children needing vaccination. • Vaccinate by appointment only (except in cases where a child accompanies another appointment) to allow staff to pull needed medical records the evening before and decrease day-of-visit paperwork. • Educate staff on the importance of their involvement in the community H1N1 response. Consider providing incentives to 	

	<p>staff asked to work overtime (e.g., appreciation party or dinners if cash incentives are infeasible).</p> <ul style="list-style-type: none"> • Schedule Saturday clinics advertising “family-centered care” – an entire family can show up and receive vaccines if they fit recommended guidelines. <p>For more information,</p> <p><i>CDC Guidelines for Setting up Clinics:</i></p> <p>http://www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm</p> <p><i>Tools and Models to Estimate Staffing:</i></p> <p>http://www.cdc.gov/h1n1flu/vaccination/statelocal/tools.htm</p>	
(Step 2)	<p>Discuss how you might set up your clinical space to efficiently administer the vaccine.</p> <p>Consider ways to handle patient flow to avoid mixing well and sick persons.</p> <p>Assign appropriate staff to coordinate and monitor the set up of vaccination areas in your clinical space.</p>	
Additional Information and Resources	<p>Review current CDC recommendations for <i>Infection Control for Patients in Healthcare Settings</i>:</p> <p>http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.</p> <p>(Please note that guidelines are updated as additional information on transmission becomes available. Check the CDC website for the most recent recommendations to inform your planning).</p> <p>Consider additional options for separating well-children receiving vaccines from children who may be ill or exposed:</p> <ul style="list-style-type: none"> • Alter scheduling – provide vaccines only on certain days, only in the evenings, or during Saturday clinics. • Vaccinate in non-traditional settings separate from sick children (office parking lot, in personal vehicles, drive thrus). • Use phone triage for directing patient flow – have one number for regular and informational calls, another for severe cases of 	

	<p>illness. Develop a script for triage to ensure high-risk patients come in to be vaccinated (are you pregnant? Do you have children in your household who are under 6 months?).</p> <ul style="list-style-type: none"> Establish separate entrances and waiting areas for well children and ill/exposed children. <p>Consider special infection control measures required for pediatric patients such as replacing waiting room toys and books with videos or asking parents to bring their own toys from home to help occupy their children during potentially longer waiting times.</p>	
(Step 3)	<p>Discuss what new needs might be created by having vaccine on hand. For example, consider extra sharps disposal, more refrigerator space, and informational brochures for patients.</p> <p>If you need assistance with certain things, check with local resources like public health or emergency management to find out what they can provide.</p>	
Additional Information and Resources	<p>Free informational brochures available from CDC: http://www.cdc.gov/h1n1flu/flyers.htm</p> <p>For additional child-friendly flu-related messages: http://www.cdc.gov/sesame.html?s_cid=healthyHabits_001 http://www.sesamestreet.org/parents/topics/health/flu/ http://www.flu.gov/psa/index.html</p>	
(Step 4)	<p>Decide who will perform what roles – e.g., assign who does certain important functions (triage/intake, directing patients to rooms, vaccinating, billing, immunization registry data entry and monitoring for adverse effects).</p> <p>Assign backups to each role. Train staff and have each person record their responsibilities and where they keep all of their supplies. Post responsibilities in the office or create job checklists.</p> <p>It may be necessary to augment staff and/or to cross train staff to perform multiple functions.</p>	
Additional	Staff augmentation strategies to consider (note- these efforts should	

Information and Resources	<p>be coordinated with local public health efforts that that may also be planning to use the same sources of additional staff for community-based clinics):</p> <ul style="list-style-type: none"> • Make a list of retired nurses and contact them to come in and assist (note- in order to obtain buy-in, it will be necessary to take steps to ensure these individuals receive the H1N1 vaccine under the recommendations for essential healthcare workers). • Use volunteer nurses and members of the Medical Reserve Corps (MRC) or Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHP). • To find a MRC unit in your area go to: www.medicalreservecorps.gov. <p>When considering cross training staff or using volunteers to provide vaccines, remember that just-in-time training may be needed particularly for volunteers who typically treat adult patients.</p> <p>The California Department of Health Services offers a series of videos providing guidelines on proper needle size, site, and techniques for vaccine administration to children and adults.</p> <p>For information on Immunization Practices and Techniques or to order training videos: http://www2.cdc.gov/nip/isd/immtoolkit/content/vacadmin/techniques.htm .</p>	
(Step 5)	<p>Consider unusual situations. Some possibilities would include:</p> <ul style="list-style-type: none"> • Media requests • How will your practice address the issue of vaccinating community members that are not typical patients? 	
(Step 6)	<p>Determine what your backup plan will be if you become overwhelmed.</p> <p>Who are you talking to in the community about your backup plans? Write down these contacts and their phone numbers.</p>	
(Step 7)	<p>Discuss how you will inform patients of your vaccine administration plan and which patients need to be reached first.</p>	

	<p>Educate high risk patients as soon as possible on their need for H1N1 vaccination.</p> <p>Identify and educate those patients that should not receive this vaccine (those who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine).</p>	
Additional Information and Resources	<p>A pre-licensure Vaccine Information Statement (VIS) for the inactivated, injectable formulation of the 2009 H1N1 vaccine is available: http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/vis-h1n1-prelicensure.pdf</p> <p>It is anticipated that a pre-licensure VIS for the live attenuated, intranasal formulation VIS will be available shortly. (Note- VIS statements will likely be updated so check the CDC website for the most recent versions before providing copies to patients).</p> <p>Other communication/education options to consider:</p> <ul style="list-style-type: none"> • Record a message that will play while patients are on hold and when the office is closed that explains your plan to provide H1N1 vaccine. • If your office has a website, keep it updated with information on your vaccine administration plan. • Send a letter to your patients outlining the procedures they should follow to receive a vaccine. Contact your local public health department to ask if they have letter templates available. 	
(Step 8)	<p>Talk to your local hospitals and public health partners and let them know about your plan. Check to see what reporting information they will want to know (e.g., "How many shots have we given out and to what populations?")</p> <p>In kind, think about what information you would like to hear from them.</p>	
Vaccine Safety Monitoring	<p>Refer to the Vaccine Safety Planning information provided by the CDC: http://www.cdc.gov/h1n1flu/vaccination/safety_planning.htm.</p> <p>Educate yourself on the Vaccine Adverse Events Reporting System (VAERS) and the procedures for submitting a report. Report forms are available online at http://www.vaers.hhs.gov/ or can be obtained by</p>	

	<p>calling 1-800-822-7967. Patients are also able to make reports to VAERS if they feel they have an adverse event to report.</p> <p>Contact your local health department to learn if they have a plan to respond to vaccine safety concerns from providers. This plan should include prompt reporting on clinically significant adverse events to VAERS.</p> <p>Plan for calls or questions about the safety of the H1N1 vaccine and potential adverse events, including questions about its similarity to the 1976 flu vaccine and use of certain ingredients: http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm.</p>	
Additional Information and Resources	Providers with Vaccine Safety concerns may also contact CDC at 800-CDC-INFO (800-232-4636).	
Evaluation		
Evaluate your progress	Plan for how you will track and record the number of patients you will vaccinate.	
Additional Information and Resources	Discuss what impact vaccination had on the clinic and what would need to be improved or resolved for the next time (After Action Performance Review).	

Important contacts

Function (What)	Name	Phone Number/ Email
Public Health Vaccine Contact		
Emergency Management Contact (supplies, power)		