
2009 H1N1 Influenza School-located Vaccination (SLV): Information for Planners

Purpose	To provide information for planning and conducting school-located 2009 H1N1 influenza vaccination clinics that target school-aged children enrolled in school and potentially other groups in the community.																																												
Target Audience	Primarily state and local public health department immunization and preparedness staff who are responsible for carrying out 2009 H1N1 influenza vaccination, but also education officials, school nurses, and others who are interested in planning and carrying out such activities.																																												
Glossary	<table><tr><td>ACIP</td><td>Advisory Committee on Immunization Practices</td></tr><tr><td>CCV</td><td>Commercial Community Vaccinator</td></tr><tr><td>CDC</td><td>Centers for Disease Control and Prevention</td></tr><tr><td>CFR</td><td>Code of Federal Regulations</td></tr><tr><td>CRA</td><td>Countermeasure and Response Administration</td></tr><tr><td>HHS</td><td>Health and Human Services</td></tr><tr><td>EMAC</td><td>Emergency Management Assistance Compact</td></tr><tr><td>FDA</td><td>Food and Drug Administration</td></tr><tr><td>FERPA</td><td>Family Educational Rights and Privacy Act</td></tr><tr><td>HIPAA</td><td>Health Insurance Portability and Accountability Act</td></tr><tr><td>IIS</td><td>Immunization Information System</td></tr><tr><td>MSF</td><td>Medical Services Firm</td></tr><tr><td>NACCHO</td><td>National Association of County and City Health Officials</td></tr><tr><td>NEMA</td><td>National Emergency Management Association</td></tr><tr><td>PREP Act</td><td>Public Readiness and Emergency Preparedness Act</td></tr><tr><td>RBC</td><td>Retail-based clinic</td></tr><tr><td>SLV</td><td>School-located vaccination</td></tr><tr><td>UCC</td><td>Urgent care clinic</td></tr><tr><td>VAERS</td><td>Vaccine Adverse Event Reporting System</td></tr><tr><td>VHP</td><td>Volunteer health professionals</td></tr><tr><td>VIS</td><td>Vaccine Information Statement</td></tr><tr><td>VPA</td><td>Volunteer Protection Act</td></tr></table>	ACIP	Advisory Committee on Immunization Practices	CCV	Commercial Community Vaccinator	CDC	Centers for Disease Control and Prevention	CFR	Code of Federal Regulations	CRA	Countermeasure and Response Administration	HHS	Health and Human Services	EMAC	Emergency Management Assistance Compact	FDA	Food and Drug Administration	FERPA	Family Educational Rights and Privacy Act	HIPAA	Health Insurance Portability and Accountability Act	IIS	Immunization Information System	MSF	Medical Services Firm	NACCHO	National Association of County and City Health Officials	NEMA	National Emergency Management Association	PREP Act	Public Readiness and Emergency Preparedness Act	RBC	Retail-based clinic	SLV	School-located vaccination	UCC	Urgent care clinic	VAERS	Vaccine Adverse Event Reporting System	VHP	Volunteer health professionals	VIS	Vaccine Information Statement	VPA	Volunteer Protection Act
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Definition	<p>School-located vaccination (SLV): Vaccination that is:</p> <ul style="list-style-type: none">• Administered on school grounds• Targets enrolled students and potentially others• Held before, during, and/or after school hours• Typically involves collaboration between public health departments and public and private schools/school districts																																												

Background

The first available doses of the 2009 H1N1 influenza (sometimes called “novel H1N1” or “swine flu”) vaccine are anticipated by mid-October. The Advisory Committee on Immunization Practices (ACIP) has recommended that people ages 6 months to 24 years; people 25-64 years who are pregnant or who have certain medical conditions, such as heart or lung disease, diabetes, weakened immune systems, blood disorders, neurologic or neuromuscular disease, and other illnesses; parents and caregivers of children less than 6 months of age; and healthcare workers and emergency personnel be considered the highest priority groups for initial vaccination (See: <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>). The priority age group includes school-aged children, who are generally ages 5-18 years. Of course, the ACIP continues to recommend annual seasonal influenza for all children, 6 months through 18 years of age (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0724a1.htm>).

Private providers (e.g., pediatricians) are unlikely to serve as the primary vaccinators of school-aged children because they cannot quickly vaccinate large numbers of children in a short period of time (Rand, 2008). In addition, children of this age infrequently access health care for preventive, non-acute care so many extra medical care visits would be required to vaccinate children in traditional provider settings (Rand, 2007). As an alternative, SLV has been widely discussed as a potentially viable option for vaccinating many school-aged children against 2009 H1N1 in a short period of time and may also be a way to reach others for vaccination.

There are benefits to holding 2009 H1N1 SLV clinics:

- Large numbers of children are found in schools
- Schools are conveniently located throughout communities
- Communities are generally familiar with and trust schools
- School facilities can generally accommodate mass vaccination clinics (e.g., the availability of gymnasiums and auditoriums, ample parking in some locations)
- School nurses, if present, may be available to assist in vaccination activities and may be familiar with the health of individual students
- School staff have access to parental contact information, which could facilitate communications (e.g., for announcing clinic dates, obtaining parental consent for vaccination)
- Others prioritized for vaccination besides enrolled students may request vaccination at vaccination events

There are potential challenges to holding 2009 H1N1 SLV clinics:

- Clinics could disrupt educational activities
- Locating adequate staff to prepare for and conduct the clinic may be difficult
- Immunization activities may need to be tailored to each school or school district, complicating planning efforts
- Handling and transporting the vaccine to many and varied locations requires considerable planning, equipment, and training

Many schools and public health departments have conducted SLV clinics in the past, but many have not. The information below, as well as the links to guidance developed by other groups (e.g., the National Association of County and City Health Officials [NACCHO] School-located Influenza Immunization School Kit, <http://www.naccho.org/toolbox/tool.cfm?id=1680>), has been designed primarily to help inexperienced but interested public health departments, schools/school districts, and others conduct successful 2009 H1N1 SLV clinics. Of course, the decision about whether or not to pursue SLV clinics should be made at the local level, since the

feasibility of holding these clinics will vary greatly by local health department, school district, and even every individual school. School officials are encouraged to review collective bargaining agreements (CBAs) with school staff prior to making decisions on how staff are to be utilized.

The following information, for the most part, assumes that the public health department will be leading the 2009 H1N1 SLV effort. The information provided focuses on vaccinating enrolled students because of the many unique challenges when SLV occurs during school hours. However, options for vaccinating other persons also are mentioned. For planners who are considering the school as a potential venue to offer vaccines primarily to non-students, general guidelines for setting up large-scale vaccination clinics are posted on the CDC H1N1 website (<http://www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm>).

Planning for the Vaccination Clinic

In addition to the information provided below about planning for SLV clinics, please also see the more general guidelines for setting up large-scale vaccination clinics posted on the CDC H1N1 website (<http://www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm>).

2009 H1N1 SLV Leadership / Initiation

The first step in planning for SLV clinics is to form partnerships between the public health department and education agencies, as well as any other organization(s) that could assist in the SLV clinics. The public health department traditionally has led SLV efforts, but a school/school district or a private organization (e.g., a commercial community vaccinator) also could take primary responsibility. Regardless of who leads or initiates the SLV effort, these partnerships with public health are essential. SLV planners may choose or be required to establish a memorandum of understanding or a similar document, that identifies the roles and responsibilities of each partner (e.g., who will be the main contacts from public health and the school/school district, who will be responsible for collecting parental consent forms and communicating with parents/guardians).

If the public health department initiates the SLV program, the first step should be to contact school district superintendents, but, it is essential to also form partnerships with the school board and to communicate with and gain support of school principals, who ultimately oversee all activities within their school. Attached is a template letter to principals (available at <http://www.cdc.gov/h1n1flu/vaccination/slv/ltr-principals.htm>). Where principals have the authority to make decisions on conducting/participating in SLV clinics autonomously, the reverse order of communication should be applied.

Population(s) Identified for Vaccination

Planners will need to identify which population(s) will be offered the opportunity to be vaccinated. As mentioned, the information contained in this document focuses on vaccination of enrolled students. Although most enrolled students will be school-aged (5-18 years), planners should be aware that some schools include students who are older than age 18 or younger than age 5.

Planners may also decide to include the following populations, for example:

- Students attending nearby schools other than the school where the SLV clinic

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- will take place
- Home-schooled children and/or school-aged children who are not enrolled in school for other reasons
 - School staff
 - Students' younger siblings and other family members
 - Other members of the community

Many factors will affect the decision to include persons other than students of the school where the SLV clinic will be held, including vaccine supply or which populations would most benefit from vaccination according to local 2009 H1N1 epidemiology.

When to Hold SLV Clinics

Planners will also need to decide whether to hold SLV clinics before, during, and/or after school hours. Below are some benefits and challenges to consider when making decisions on when to hold SLV clinics.

SLV during school hours

Benefits

- Parents/guardians do not need to take time off work because their children can be vaccinated without them being present.
- Children are present in large numbers.
- Vaccinations can be conveniently provided to school staff, if desired and appropriate.
- Because parental consent is obtained prior to the clinic, there is some lead time during which planning for adequate staffing, vaccine, and medical supplies can take place.

Challenges

- Parental consent to vaccinate children must be obtained ahead of time; coordination will be required to send consent forms to parents/guardians and allow time for them to be returned to school officials.
- Some parents/guardians object to not being present when their children are vaccinated (but parents/guardians entering the school during the SLV clinic could be logistically problematic).
- Disruption of class time may be unacceptable to parents, students, and school administrators.
- Typically, it is not practical to invite others in the community who are not enrolled students, but who could otherwise be vaccinated at a SLV clinic.

SLV before/after school hours

Benefits

- Persons other than school-aged children can be vaccinated, if desired, appropriate, and logistically feasible.
- Parental consent to vaccinate children can be obtained at the time of service, avoiding the challenges of getting consent forms to, and back from, parents/guardians.
- Clinics could be held in one or several centrally-located schools instead of every school, which may be cost-saving and more feasible for planners and those who conduct the clinic.

Challenges

- By some reports, clinic efficiency may be decreased when parents/guardians are present (children may be more likely to protest/cry in the presence of parents/guardians).
- Extending school hours may require overtime for vaccinators and school staff, incurring additional expenses.
- Parents/guardians may find it difficult to bring the child to clinics held in the evenings or on the weekends.

In addition, regardless of whether a 2009 H1N1 SLV clinic is held during or before or after school hours, school officials may need to consult with local union representatives if holding such a clinic has an impact on staff members' rights under a collective bargaining agreement.

Planning for Adequate Staff

Implementing SLV clinics may require staffing capacity that exceeds that of the local public health department (please see the following link that offers several tools for planning adequate staff: <http://www.cdc.gov/h1n1flu/vaccination/statelocal/tools.htm>). Because of this, planners should consider recruiting additional staff, both medical and non-medical. Federal funds for the implementation of the H1N1 campaign are intended to cover the costs of organizing and conducting these clinics.

Potential roles and duties for additional, non-public health department staff could include the following (Note: licensure/liability issues are discussed below under "Legal Issues"):

Non-medical, non-public health department staff:

- Assembling, distributing, and collecting vaccine information, consent forms, and other materials
- Communicating with parents/guardians (e.g., to encourage return of consent forms if consent is required prior to the clinic day)
- Assisting with the promotion of the clinics (e.g., placing posters, posting information on school website, communicating with local radio/television/newspaper)
- Assisting with clinic flow and escorting students to and from the vaccination site
- Verifying the identity of each child to be vaccinated to ensure that parental consent was given
- Assisting with the transportation of vaccine and other materials to and from clinic sites
- Providing security
- Tracking and entering vaccination information into immunization registries, Countermeasure and Response Administration (CRA) reporting systems, or other databases (see: http://www.cdc.gov/H1N1flu/vaccination/statelocal/pdf/H1N1_DosesAdministered.pdf, and <http://www.cdc.gov/phln/activities/applications-services/cra/h1n1response.html>).

Medical, non-public health department staff, depending on licensure and training:

- Preparing and/or administering vaccines
- Ensuring that vaccination medical screening eligibility has been met
- Evaluating children for illness when they present to the clinic for vaccination

School Staff

School staff, including school nurses, teachers and teachers' assistants, security and maintenance personnel, and other staff, can contribute greatly to the success of a 2009 H1N1 SLV clinic. These staff members are familiar with the students, the school facilities, and the administrative structure of the school. School nurses and teachers may be familiar with students' personalities, pre-existing health conditions, and their parents/guardians. School nurses, who are present in many, but not all, U.S. elementary and secondary schools, can play a critical role in SLV clinics by answering questions from parents and educating school staff about 2009 H1N1, the consent process, and the SLV clinic. School nurses can also serve as the liaison between the public health department and the school community.

Although school nurses and other staff are likely to be willing to provide assistance, competing priorities and other school responsibilities may serve to limit their involvement. Roles and responsibilities, and the degree to which school staff are involved in the SLV clinic will vary from school to school and should be determined and defined by partners in advance of the clinic. In many cases, school administrators may determine the roles their staff will play.

For each participating school, a liaison or point of contact should be identified through which planning communications should be directed. Identifying such a person has been recognized as a key to the successful implementation of SLV programs (see: NACCHO School-located Influenza Immunization School Kit, <http://www.naccho.org/toolbox/tool.cfm?id=1680>). Regardless of the degree of school staff involvement, the SLV clinic should be viewed as a partnership between staff from public health and the school/school districts, in addition to any other organizations that participate.

The following lists activities for which school and partner organization staff may wish to take responsibility.

- Advertising the SLV clinic, perhaps using materials supplied by the public health department.
- Distributing to parents/guardians (e.g., via students, direct mailings, or by other means) informational materials and parental consent forms authorizing their child to be vaccinated, subsequently collecting and tracking the return of consent forms, and following up on students who have not submitted consent forms. These activities may be coordinated by school nurses or by teachers (e.g., for their homeroom class).
- Screening returned consent forms for completeness and ensuring that medical eligibility for vaccination has been verified.
- Identifying a location within the school where informational meetings, training, and the SLV clinic will take place; working with public health staff to establish clinic times/dates.
- On scheduled clinic days, escorting students to and from classrooms to the clinic, verifying the identity of the student to be vaccinated, and ensuring that parental consent has been properly given prior to vaccination.
- Communicating vaccination information to the vaccinee's primary health care provider
- Alerting the vaccinee and his/her parent/guardian of plans for the administration of the second dose.

It also is important that school staff are able to answer questions from parents or others about the SLV clinic or direct questions to the appropriate staff member(s). School districts and schools should consider identifying a single spokesperson and also provide information on their websites, to the extent feasible. Questions may be

directed to the school superintendent's office, school board members, school nurses, teachers, school secretaries, or others; however, all school staff should be appropriately educated about 2009 H1N1 and the SLV clinics and know where to direct more complex questions.

Volunteers

Volunteers can serve as an excellent source of SLV clinic staff and may even be considered an essential component of an SLV program, depending on the number of SLV clinics planned within a local jurisdiction. Volunteers can fill many roles in SLV clinics, both non-medical and medical.

For example:

Non-medical Volunteers Parents of school children could be helpful in conducting the SLV clinic. Other groups to consider are fraternal and service organizations, large local employers, area faith groups, medical service organizations, and students from local colleges and professional schools. Law enforcement, hospitals, and for-profit organizations (e.g., local insurance companies) also may provide staff.

Students of the school or school district where the SLV clinic will take place are another potential source of volunteers. In addition to providing a positive experience for students, peer involvement may increase student participation in the program considerably.

Medical Volunteers For medical staffing needs, planners may consider contacting area colleges that grant degrees in health-related fields, such as medicine, nursing, dentistry, and pharmacy, to recruit staff, students, or alumni willing to provide assistance with SLV clinics. Planners may also consider soliciting assistance from retired health care professionals.

Contractual Staff Temporary employment agencies may be a resource to hire both medical and non-medical staff to assist with SLV clinics. Other potential staffing sources include private, for-profit organizations, collectively known as commercial community vaccinators (CCV). In addition to temporary staffing agencies, CCV also can be hired to plan and conduct SLV clinics.

Many of these organizations are experienced in operating seasonal influenza vaccination clinics for children and adults. Some have partnered with schools to conduct SLV clinics or worked with local public health departments in partnership with schools. Planners interested in staffing SLV clinics using a commercial group can refer to the following document that defines the different categories of CCVs (available at <http://www.cdc.gov/h1n1flu/vaccination/slv/ccv-definitions.htm>).

Challenges of Using Non-public Health Department Staff in SLV Clinics

All SLV clinic staff and volunteers will need to be trained to perform their duties. Working with children is a specific skill which some medical staff may not be experienced or comfortable with.

- Although not specific to vaccinating children, planners might find the information in the following CDC websites helpful for training purposes: www.cdc.gov/vaccines/ed/webcasts.htm#4, and www.cdc.gov/vaccines/ed/encounter08/imencounter-resources.htm
- Schools may require background checks for staff who will be present on school property. Many staff may have already undergone background checks conducted through their organizations. For those who require background checks, the process may be quite lengthy and will vary locally.
- Planners may consider a contingency plan to allow for rapid infilling of extra staff when relying heavily on the contribution of volunteers, especially if local outbreaks of influenza are being experienced.

SLV Clinic Promotion and Education

Education of students and parents, as well as school staff, may contribute to the success of SLV programs (Wilson, 2001; Guajardo, 2002).

Students

Students may be more likely to participate in a SLV program when they thoroughly understand the benefits and risks of vaccination. Classroom-based instruction and school-wide assemblies have been effective in educating students prior to immunization (Wilson, 2000; Boyer-Chuanroong, 1997; Woodruff, 1996). For schools willing to include classroom-based instruction as an element of their vaccination program, planners may consider providing teachers and school nurses with ideas for lesson plans (Goldstein, 2001). This represents an ideal opportunity to emphasize the need for annual seasonal influenza vaccination -- including during the 2009-2010 influenza season -- regardless of whether this vaccine will be provided at the school, and emphasizing hygiene measures to prevent the spread of influenza and other common causes of illness in children.

Parents / Guardians

Of course, because parents/guardians must provide consent for their child to be vaccinated, parent education also is important. A variety of methods, including public service announcements, radio campaigns, bulletins, and announcements on school websites, have been used to promote vaccination programs to parents/guardians (see: NACCHO School-located Influenza Immunization School Kit, <http://www.naccho.org/toolbox/tool.cfm?id=1680>). Messages could also emphasize the importance of annual seasonal influenza vaccination and other means to prevent the spread of influenza and other illnesses. Depending on the availability of resources, public health departments may establish a telephone line or provide a website or email address parents could use to access information and ask questions in the weeks before, during, and after the vaccination program (Carpenter, 2007).

Teachers and Other Staff

In past SLV clinics, teacher support and participation has been perceived to be linked to the success of SLV programs, and students have reported that teacher influence was an important

factor in returning consent forms (Tung, 2005; Unti, 1997). As mentioned in the “Planning for adequate staff” section, it is important that school staff are educated about the vaccination program. Educated school staff are able to answer questions from parents and others about the program, and are more likely to emphasize the importance of vaccination and provide vaccination-related lessons to students (Tung, 2005; Boyer-Chuanroong, 1997). After-school teacher workshops have been used as a method of educating school staff (Boyer-Chuanroong, 1997; Unti, 1997; Goldstein, 2001).

Informing and Enlisting the Support of Health Care Providers

In the U.S., children are vaccinated primarily in their pediatrician’s or family medicine doctor’s office (Groom, 2007). Because the idea of vaccinating children at school may be unfamiliar to some parents/guardians, there may be reluctance to consent to 2009 H1N1 vaccination at school. Parents/guardians may seek the advice of others, including their child’s health care provider (Woodruff, 1996). For this reason, the success of SLV programs also will be enhanced by enlisting the support of local health care providers, especially pediatricians, family practitioners, obstetrician/gynecologists (since they often serve as primary care providers for adolescent girls), and community health clinics. Attached is a template letter to providers (available at <http://www.cdc.gov/h1n1flu/vaccination/slv/ltr-hcp.htm>).

Hopefully, most providers will be supportive of the SLV clinics, but some may be concerned about vaccinations occurring outside of their offices, especially with regard to keeping their patient records up-to-date and having adequate information in case a patient seeks care for a possible vaccine-related adverse event. The need to conduct SLV programs to ensure children are vaccinated in a timely manner can be explained given the likelihood that providers will be busy treating ill patients. Keeping providers informed about planned SLV clinics also will help them estimate how much 2009 H1N1 vaccine they will need to order for their own patients.

Preparing Forms and Letters to Provide to Parents / Guardians

The following are suggestions on the development of materials that should be delivered – via the child, mail, and/or email - to parents/guardians to inform them of the planned SLV clinic and solicit their permission to vaccinate their child. Each of the following materials should be translated and available in various languages, as locally appropriate.

Letter to parents/guardians:

Among materials sent to parents/guardians should be a letter announcing that 2009 H1N1 SLV clinics will be offered at their child’s school. Typically, this letter is sent out as a cover letter to accompany other materials, including the consent form, information about the vaccine, and when the SLV clinics are scheduled to occur. Such a letter also could be sent well in advance of the planned SLV date, perhaps even before vaccine is available in the area.

The letter to parents/guardians should include:

- 1) an explanation about why 2009 H1N1 vaccination is recommended for their children,
- 2) an announcement that 2009 H1N1 vaccine will be offered at the school, along

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- with the clinic date(s) for both doses (if possible to determine),
 - 3) a request for parental consent, and
 - 4) contact information in case parents/guardians have questions or concerns.

(Template letters for parents available at <http://www.cdc.gov/h1n1flu/vaccination/slv/ltr-parents-consent.htm> and <http://www.cdc.gov/h1n1flu/vaccination/slv/ltr-parents-clinics.htm>.)

Parental Consent Forms

The requirement to seek parental consent prior to vaccination, and the exact format and elements that must be included on a standard consent form, generally are not governed by federal law or regulation. Instead, requirements for informed consent are legislated or regulated by each state or jurisdiction, including the circumstances under which minors can consent to their own medical treatment.

Attached are two templates that SLV program planners may use as starting points for developing consent forms in accordance with applicable state and local laws and requirements. These templates were developed for administration of vaccine licensed by the Food and Drug Administration. The template forms are not adequate for consent to administer vaccines under an investigational new drug application or under an Emergency Use Authorization.

While consent to be vaccinated is generally not regulated by federal law, federal law (as well as state law) may regulate the vaccinator's use or disclosure of individually identifiable health information regarding the child.

The first template consent form contains screening questions for the injectable formulation of the vaccine, and the second form includes screening questions about both the injectable and the intranasal formulations. The choice of which consent form(s) to distribute to parents/guardians will depend on which vaccine formulation (live-attenuated intranasal vaccine [LAIV], inactivated injectable vaccine, or both) will be offered at the SLV clinic.

In addition, both template consent forms include the data elements that are required to be reported to the CDC during the early phase of the vaccination program:

- 1) Location,
- 2) Date of vaccine administration,
- 3) Age in broad age intervals (for school-aged children, the relevant intervals would be 24-59 months, 5-18 years, or 19-24 years), and
- 4) Whether the dose administered was the first or second, assuming a two-dose vaccine series (see: http://www.cdc.gov/H1N1flu/vaccination/statelocal/pdf/H1N1_DosesAdministered.pdf, and <http://www.cdc.gov/phln/activities/applications-services/cra/h1n1response.html>).

(Template consent forms available at <http://www.cdc.gov/h1n1flu/vaccination/slv/word/h1n1-im-consent-form.doc> and <http://www.cdc.gov/h1n1flu/vaccination/slv/word/h1n1-combination-consent-form.doc>.)

Below are notes about each section on the template consent forms:

Section 1 | Information about child to receive vaccine: This section includes suggestions for collecting personal and demographic information.

Section 2	Screening for vaccine eligibility: This section includes standard vaccination eligibility screening questions for either the injectable or both injectable and intranasal formulations of the vaccine.
Section 3	Consent: This section includes a statement and signature line for parents/guardians to consent to or decline vaccination on behalf of their child. Also, planners may consider including an option for parents/guardians to select the type of vaccine (e.g., intranasal, injectable, or no preference) they prefer be given to their child with a statement that the preference will be honored depending on vaccine availability and the child's eligibility. Note that state laws vary regarding whether one parental signature will suffice for both doses.
Section 4	<p>Permission to release information: Student information contained in the vaccine consent form may be protected by state or federal privacy laws or regulations. Section 4 is reserved for consent or authorization for disclosures of certain vaccination, medical, personal, and/or demographic information. Requesting such authorization may be recommended or necessary, depending on local needs and/or laws such as the Family Educational Rights and Privacy Act (FERPA) or the Health Insurance Portability and Accountability Act (HIPAA).</p> <p>The following are examples of authorizations that could be sought by SLV program planners including a statement with a request for a parental signature on the consent form:</p> <ul style="list-style-type: none"> • The release of information to public health authorities (e.g., for entry into an immunization registry for federal 2009 H1N1 reporting requirements) • The release of information to the child's health care provider (e.g., for inclusion in the child's health care record) <p>The entity conducting the vaccination program is responsible for only using and disclosing a child's health information consistent with applicable laws. For example, the entity should know whether it is subject to the HIPAA Privacy Rule, which only applies to certain health care providers, to health plans and to health care clearinghouses, to FERPA, which only applies to educational agency or institutions receiving Department of Education funding, and/or to other Federal or state laws.</p> <p>Entities subject to the HIPAA Privacy Rule may use or disclose a minor's health information with the signed authorization of the parent or a guardian with authority to make health care decisions for the child using a form that meets HIPAA requirements or without such authorization for treatment purposes and certain public health and other purposes. See discussion of FERPA and HIPAA beginning page 19 for further information.</p>
Section 5	Vaccination record: This section includes suggestions for collecting information regarding the vaccine and its administration.

Optional Advanced Consent

State and local planners may consider distributing consent forms to parents in advance of 2009 H1N1 vaccine licensure. The benefits of such a procedure, if determined to be legally viable and feasible in the jurisdiction that will be offering 2009 H1N1 SLV clinics, are that vaccine may be expeditiously given to consented children as soon as it is received by the vaccinator, and planners may be better able to plan for adequate staff, vaccine, and supplies.

To provide parents/guardians with information on which to base their consent decision, parents/guardians could be given the attached pre-licensure 2009 H1N1 Influenza Vaccine Information Statement (VIS), which describes the best current understanding of the expected risks and benefits of the 2009 H1N1 vaccine (see pre-licensure VIS for the inactivated, injectable formulation of the vaccine: <http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/vis-h1n1-prelicensure.pdf>. The VIS for the live attenuated, intranasal formulation will be provided as soon as it is available), along with a cover letter (see template cover letter: <http://www.cdc.gov/h1n1flu/vaccination/slv/ltr-parents-consent.htm>). To document their consent decision, parents would also need be given an appropriate consent form (see template consent forms: <http://www.cdc.gov/h1n1flu/vaccination/slv/word/h1n1-im-consent-form.doc>, <http://www.cdc.gov/h1n1flu/vaccination/slv/word/h1n1-combination-consent-form.doc>) to complete and return to the school.

If parental consent for vaccination is obtained substantially in advance of the time that the vaccine is to be administered to the child, a mechanism must be provided for the parent/guardian to withdraw consent prior to the time of vaccination, if desired. A mechanism should also be provided for a parent/guardian who initially declines to give consent for his/her child to be vaccinated to subsequently change that election and give consent for the child to be vaccinated. Additionally, if it is anticipated that LAIV will be offered, plans should be in place to confirm that the child has not received another live vaccine (e.g., varicella or measles, mumps, rubella [MMR] vaccines) within four weeks of the SLV clinic.

If substantial changes are made to the final VIS and/or consent forms when the 2009 H1N1 vaccine is licensed, parents/guardians must be provided with the updated VIS and/or consent form and be given an opportunity to change their consent status, if desired.

If planners decide to pursue consent in advance of vaccine licensure, as described above, an informational packet also could be sent slightly in advance of the clinic (e.g., two or three weeks in advance). This procedure could serve to announce or remind parents of the clinic date, provide an official VIS form for those who have not received one, and remind parents/guardians of mechanisms to change their consent status.

Planners should discuss this approach with state and local legal advisors before deciding to implement it. Planners also should consider whether state/local law would require separate consents for administration of each of a two dose vaccine series.

Important information about the use of the template consent form is provided above. Please also refer to the section below on "Legal issues" for important information on liability, licensing, FERPA, and HIPAA.

Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by the CDC that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. They also include information about indications and eligibility for each vaccine. An appropriate VIS (depending on which formulation of 2009 H1N1 vaccine is being offered—intranasal or injectable) should be included among materials provided to parents/guardians before and after vaccine administration. A pre-licensure VIS for the inactivated, injectable formulation of the 2009 H1N1 vaccine has been included as an attachment in the section above on optional advanced consent, and it is anticipated that a pre-licensure VIS for the live attenuated, intranasal formulation will be available shortly. These VISs will be updated, if necessary, when the vaccines are licensed by the FDA.

Maximizing Participation in the SLV Program

A variety of strategies for maximizing participation in SLV programs have been successfully implemented in past SLV programs. These strategies are summarized below.

Consent Form Dissemination, Collection, and Follow-Up

Sending information packets home with students is commonly used and appears to be effective relative to sending the information home via US mail (IZ Xtreme, <http://www.co.el-dorado.ca.us/publichealth/IZXtremeReport.html>; El Amin, 2009). Schools also should consider making consent forms available on-line, either through the school website (if available) or via email (schools and/or parent organizations may have pre-established list serves for students' families) (Boyer-Chu, 2008; NACCHO School-located Influenza Immunization School Kit, <http://www.naccho.org/toolbox/tool.cfm?id=1680>). Additionally, high schools might want to make consent forms available on-site for eligible students who do not require parental consent (e.g., students aged 18 years or older) (NACCHO School-located Influenza Immunization School Kit, <http://www.naccho.org/toolbox/tool.cfm?id=1680>).

Limited data suggest that return rates are higher when teachers (rather than nurses or other school staff) are responsible for collecting consent forms (Tung, 2005). To facilitate follow-up, schools may consider setting an absolute deadline for return of consent forms (Wilson, 2001).

If resources are available, school staff should attempt to follow up with students who do not initially return the forms (Boyer-Chuanroong, 1997). For this reason, consent forms should include an option for the parent/guardian declining vaccination so that school staff can easily identify students who have not returned consent forms and distinguish them from students whose parents/guardians declined vaccination. Also, including a "decline" option allows incentives (see below) to be based on the total number of forms returned, regardless of whether parents/guardians consented to or declined vaccination.

Incentives

Student incentives can motivate students to return completed parental consent forms (Boyer-Chuanroong, 1997). Individual incentives for students who return completed consent forms or peer or group incentives for classes with a high proportion of students who returned completed consent (e.g., increased class recess time), may be considered (Boyer-Chuanroong, 1997; Uniti, 1997; Guajardo, 2008; Wilson, 2001; NACCHO School-located Influenza Immunization School Kit, <http://www.naccho.org/toolbox/tool.cfm?id=1680>).

A randomized controlled study of different types of incentives found that peer or group incentives were more effective than individual incentives (Unti, 1997). To reduce or eliminate costs associated with providing student incentives, schools may consider approaching local merchants or community organizations for donations, coupons, or gift certificates (Boyer-Chu, 2008). If planners decide to use incentives, they should be based on the number of consent forms returned complete, regardless of whether parents consented to or declined vaccination.

Thus, in order to use incentives, consent forms must include an option for parents to either consent to or decline vaccination (see parental consent form discussion and templates in the section on "Preparing forms and letters to provide to parents/guardians").

Because teacher support has been identified as an important factor for maximizing participation in school-located vaccination programs (Tung, 2005; Goldstein 2001), when resources are available, teachers who actively participate in the vaccination program could be provided with appropriate incentives (Boyer-Chuanroong, 1997; Goldstein, 2001; Cassidy, 1998). A simple note expressing appreciation may also be an effective reward (Boyer-Chuanroong, 1997). In addition, it may be necessary to consult with local union representatives if an incentive system has an impact on staff members' rights under a collective bargaining agreement.

Again, incentives should be based on the number of consent forms that are returned and complete, regardless of whether parents consented to or declined the vaccination.

SLV Clinic Day Logistics

Published guidelines for setting up large-scale vaccination clinics are at <http://www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm>. These guidelines were not developed specifically for 2009 H1N1 SLV vaccination. However, most of the suggested approaches are relevant, especially to SLV clinics held during non-school hours. Additional considerations apply to SLV clinics held during school hours.

These challenges, along with tips and examples of how to manage them, are outlined below:

For SLV clinics held during school hours:

- Rules on whom may be present in the school building during school hours, may vary. Communicate well in advance about these issues and plan accordingly. Additional security staff to monitor safety and help with traffic flow may be necessary.
- Since parents/guardians may not be present when students are vaccinated, processes need to be in place to ensure that only children for whom parental consent was obtained are vaccinated. This process of confirming the identity of children is easiest if school staff (e.g., teachers and school nurses) are overseeing the process.
 - Placing labels and/or name tags on children (usually younger students) can help to reduce immunizing the wrong students (NACCHO School-located Influenza Immunization School Kit,

<http://www.naccho.org/toolbox/tool.cfm?id=1680>), although monitoring is suggested as these identifiers can be exchanged by children.

- Asking multiple questions in addition to the child's name (e.g., parent/guardian names, street address) may be helpful.
- Processes need to be in place for orderly vaccination of children. Staff will be needed to escort students to and from the clinic site.
 - Often, children are escorted classroom by classroom. For older students who change classrooms throughout the day, it may help to focus on one particular class that is attended at some point by most or all students (e.g., Language Arts/English)
- Despite some parents/guardians providing consent for their child to be vaccinated, it may not be possible to vaccinate the child on clinic day for reasons such as illness, child refusal, or discovering a contraindication. In this case, it is essential that parents/guardians are informed that the child was not actually vaccinated. This could be accomplished by returning a form to parents/guardians via the child or via U.S. mail, sending the parent an email message, and/or calling the parent on the telephone. It may be helpful to designate one SLV clinic staff member to be in charge of this important task.

Administering Vaccine and Preventing, Managing, and Reporting Possible Vaccine-related Adverse Events

Please consult the following links for publications that provide guidance on administering vaccine and preventing/managing adverse events, including syncope, which is most common in adolescents:

(<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm> and <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm>)

Health care providers and parents are encouraged to report clinically significant adverse events after 2009 H1N1 vaccine or any vaccine to the Vaccine Adverse Event Reporting System (VAERS) (<http://vaers.hhs.gov/>).

A report should be submitted even if reporter is not certain that the vaccine caused the event. Reports may be filed securely online, by mail, or by fax.

Vaccine Storage and Handling

Please consult the following links for information on vaccine storage and handling:

<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>, http://www.usamma.army.mil/cold_chain_management.cfm, and <http://www.usamma.army.mil/assets/docs/CCM%20Brief.pdf>

Recording, Reporting, and Tracking Vaccination Information

Many states are planning to use their state immunization information system (IIS) to collect information on the 2009 H1N1 vaccine administration. Reporting to the IIS is not a federal mandate, but may be required under state law. These systems may be an effective method to consider when electronically transmitting data to a public health department or creating a general data file to be kept by the vaccinator in case of a possible vaccine-related adverse event. Some IIS can produce a vaccination history which can be provided to the parent/guardian and subsequently shared with the child's health care provider.

The use of an IIS may also facilitate federal 2009 H1N1 vaccine reporting requirements through the Countermeasure and Response Administration (CRA) system (see http://www.cdc.gov/H1N1flu/vaccination/statelocal/pdf/H1N1_DosesAdministered.pdf, and <http://www.cdc.gov/phn/activities/applications-services/cra/h1n1response.html>).

The CRA system will require reporting 2009 H1N1 vaccination information aggregated by location, date of vaccine administration, age group, and dose number. Aggregate numbers for each variable are required to be reported on a weekly basis to the designated public health authority. The IIS can facilitate this reporting function to the CRA system for those interested in using it.

Planners may also wish to consider distributing the attached Influenza Vaccination Record cards (available at <http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/h1n1vaxrecord.pdf>) to vaccinees (e.g., to parents via vaccinated children). Information can be recorded on these cards about the vaccine provider, lot number, manufacturer, etc., which can be shared with the vaccinee's primary health care provider. Information can also be recorded on the card about when the second dose is needed and what to do in case of a possible adverse event. These cards will be shipped along with the H1N1 vaccine ancillary supplies.

Legal Issues

States should consult their legal counsel for advice concerning the applicability of legal immunity, licensure, and privacy laws that may exist with respect to persons involved in vaccination programs. The paragraphs below provide general summaries of some relevant legal authorities, but the list is not intended to be exhaustive.

The Public Readiness and Emergency Preparedness Act

Liability and licensing

The Public Readiness and Emergency Preparedness (PREP) Act authorizes the Secretary of the Department of Health and Human Services ("Secretary") to issue a declaration ("PREP Act declaration") that provides immunity from tort liability (except for willful misconduct) for claims of loss related to the administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency. This immunity extends to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. On June 15, 2009, the Secretary of Health and Human Services (HHS) issued a declaration extending the PREP Act's liability protections to 2009 H1N1 influenza vaccine. Other 2009 H1N1-related declarations have also been issued, e.g., antivirals, influenza diagnostics, certain respiratory protection and support devices. Those declarations can be found at the following website: <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>.

Immunity from tort liability means there is no legal tort claim that can be pursued in court, whether state or federal. Tort claims precluded by a PREP Act declaration include all claims (except for willful misconduct) under Federal or State law for any type of loss including death; physical, mental, or emotional injury; fear of such injury; or property damage or loss, including business interruption loss, with any causal relationship to any stage of development, distribution, administration or use of the covered countermeasure recommended in the declaration.

The PREP Act provides immunity to “covered persons,” which includes a “program planner.” Under the Act, a program planner means a State or local government, including an Indian Tribe; a person employed by the State or local government; or other person (such as a private sector employer or community group) who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with the Secretary’s declaration. Public health departments and schools administering 2009 H1N1 SLV programs likely would be covered by the Act’s protections as “program planners.”

Immunity is also extended to “qualified persons,” which includes

- (1) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense covered countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or
- (2) a person within a category of persons identified as qualified in the Secretary’s declaration. The Secretary did not identify any additional qualified persons under this second category in the declaration for 2009 H1N1 influenza vaccine. However, governors may have emergency response authorities to authorize individuals to provide vaccine who are otherwise unlicensed. Such individuals would fall under the first category.

Immunity from liability is not available for death or serious physical injury caused by willful misconduct. The PREP Act also does not extend immunity to acts that occur outside the scope of the declaration or for violations of laws that are not tort claims, such as civil rights or labor laws.

The PREP Act also authorized a “Covered Countermeasures Process Fund” to provide compensation to eligible individuals who suffer specified injuries from administration or use of a countermeasure pursuant to the declaration. Any requests for compensation must be filed within one year of administration or use of the countermeasure. Requests would go to the HRSA Preparedness Countermeasures Injury Compensation Program (<http://www.hrsa.gov/countermeasurescomp/default.htm>). Compensation may be available for medical benefits, lost wages and death benefits to eligible individuals for specified injuries. Any compensation will be reduced by public or private insurance or worker’s compensation available to the injured individual.

State and Local Government Immunity

Officials of state and local governments may also have "official" or "governmental" immunity under state legislation, municipal ordinances, or as otherwise provided for by common law. These laws may differ depending upon the level of government, the nature of the official function, the presence or absence of malice, and the degree of alleged negligence. In some instances, however, this immunity may only be provided to public officers while exposing their government employers to at least limited liability. Officials may wish to contact State and local legal advisors on these matters.

Volunteer Health Professionals - Reciprocal

Licensing

A number of mechanisms may be available to enable volunteer health professionals (VHPs) to render assistance in states in which they are otherwise unlicensed.

Mutual aid compacts, such as the Emergency Management Assistance Compact (EMAC), enable VHPs, as well as paid health professionals, licensed and/or credentialed in participating states to render assistance when the governor of an affected state declares an emergency or disaster and requests aid from a participating state pursuant to the compact. The EMAC system is administered by the National Emergency Management Association (NEMA), which is part of the Council of State Governments. States may also work directly with other states to request aid pursuant to each state's EMAC or other mutual aid compact.

State emergency management laws may provide for licensing reciprocity. When a governor has declared an emergency or disaster, some states' emergency management laws may allow VHPs who are licensed in another state to render aid in the affected state. In addition, once a state governor declares an emergency, the governor may have emergency powers which enables the governor to modify or suspend temporarily statutes and regulations that conflict with the execution of emergency management functions. States may still need to implement a process during an emergency to verify out-of-state licenses and/or credentials. VHPs may also affiliate with an organization, such as the Red Cross, which has negotiated reciprocal licensing agreements with a particular state. During an emergency, VHPs may be able to work through the Red Cross to provide aid in another state.

Liability protections for VHPs

Various state and federal laws provide protection to VHPs from civil liability through indemnification or immunity. Indemnification provisions allow civil cases against VHPs to go forward and for VHPs to be held liable for their actions, but provide for the defense (usually by the state) of the action and for reimbursement of VHPs found civilly liable. Immunity provisions prevent a civil liability claim from going forward, thus shielding certain VHPs from civil liability for their actions (although VHPs may need to pay legal costs at the outset to assert an immunity defense). Immunity provisions usually do not shield VHPs from egregious misconduct such as gross negligence or willful and wanton misconduct.

Mutual aid compacts such as EMAC may provide liability protections to certain VHPs, as well as paid health care professionals, whose services have been requested through the compact. For example, EMAC provides that officers and employees of the responding state are treated like agents of the requesting state for tort liability and immunity purposes. In addition, EMAC provides that no party state or its officers or employees are liable for negligence while rendering aid, although such persons are liable for willful misconduct, gross negligence, or recklessness. Whether a particular VHP is considered an "officer or employee" of the responding state may vary state to state depending on the specific facts at issue and state laws involved.

Once state governors declare an emergency, most, if not all, state governors have emergency powers which enable them to make, amend, or rescind temporarily orders, rules, and regulations that are necessary to carry out the state's emergency functions. During an emergency, a governor may have authority to issue an executive order extending tort liability protections to out-of-state health care providers. In addition, many states have enacted emergency management statutes which extend immunity or indemnify VHPs (as well as paid health care professionals) engaged in emergency management functions when the governor has declared a state of emergency.

All states have statutes called "Good Samaritan" laws which provide some legal protection for an individual who provides immediate emergency medical care or assistance at the scene of an accident or other emergency. However, Good

Samaritan laws differ from state to state as to whom they protect, under what circumstances civil immunity is afforded, and how far the protection extends. As is true for most other forms of tort liability protections, most Good Samaritan laws distinguish between ordinary and gross negligence and do not shield individuals from liability if they act with gross negligence or willful or wanton misconduct.

Some states have enacted laws that provide some tort liability protection to VHPs who volunteer their skills to help patients who cannot afford their care. State volunteer protection acts are distinct from Good Samaritan laws which apply only in emergency situations. However, like Good Samaritan laws, the protections afforded by state volunteer protection acts vary state to state and officials may wish to contact State legal advisors on these matters.

The federal Volunteer Protection Act (VPA) of 1997 immunizes volunteers of nonprofit organizations or governmental entities from civil liability for harm resulting from the volunteers' actions. The Federal VPA provides that volunteers will not be liable for economic harm caused by their ordinary negligence during the performance of their volunteer activities so long as the activities are within the scope of the volunteers' responsibilities in the non-profit organization or governmental entity.

Volunteers must be licensed, certified, or authorized to perform those acts that require such authorization. The immunity protections do not extend to harm caused by operation of a motor vehicle or similar craft. Additionally, limits on liability do not apply to crimes of violence, hate crimes, sexual offenses, civil rights offenses, or when the volunteer was under the influence of alcohol or drugs at the time of the misconduct. It does not affect the liability of the nonprofits or governmental entities themselves.

Family Educational Rights and Privacy Act (FERPA)

FERPA is the federal law, administered by the U.S. Department of Education, which protects the privacy of student education records, including health records, maintained by educational agencies and institutions. The law applies to all educational agencies and institutions that receive funds under a program administered by the U.S. Department of Education. FERPA generally prohibits the disclosure, without prior written consent, of education records or personally identifiable information (PII) from education records to outside entities, although there are a number of exceptions to the requirement of prior written consent. (see: <http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html>).

The applicability of FERPA will vary based on whom is conducting the school-located vaccination clinic as follows:

- If a public health department, or an entity acting on its behalf (e.g., a commercial community vaccinator with whom the public health department developed a contract), conducts the clinic and maintains the student's records, FERPA does not apply to the vaccination records because they are maintained by the public health department.
- If a school, school district, or an entity acting on its behalf (e.g., a commercial community vaccinator with whom the school or district developed a contract) conducts the clinic and maintains the student's records, FERPA applies to the vaccination records because they are maintained by the school or school district.
- If an entity, other than the public health department or the school/school district, conducts the clinic (e.g., a commercial community vaccinator not

**FERPA
Applicability
During 2009
H1N1 Activities**

under a contract with the school or the public health department) and maintains the student's records, then FERPA does not apply to the vaccination records because they are not maintained by an educational institution or agency or a party acting for an educational institution or agency.

Under the FERPA regulations at 34 Code of Federal Regulations (C.F.R.) Part 99, many disclosures of PII from education records of students require signed and dated parental consent. However, when a student turns 18 years of age or attends an institution of postsecondary education, the signed and dated consent must be obtained from the student. 34 C.F.R. 99.3 (definition of "Eligible student") and 99.5. The FERPA regulations provide that the prior written consent must specify the records to be disclosed, the purpose of the disclosure, and the party or class of parties to whom the disclosure may be made. 34 C.F.R. 99.30. For example, in the absence of a health or safety emergency, signed and dated consent is generally needed for a school to release PII from education records to public health authorities (e.g., for entry into an H1N1 immunization registry) or to the child's health care provider (e.g., for inclusion in the child's health care record).

Certain disclosures may be made without prior written consent. 34 C.F.R. 99.31. For example, a disclosure may be made without prior written consent to other school officials within the educational agency or institution whom the agency or institution has determined to have legitimate educational interests (e.g., school officials may be informed that a student has the H1N1 virus and has been advised to stay at home; the disclosure is needed so that school officials can monitor whether that student nevertheless attends school or a school-related activity). 34 C.F.R. 99.31(a)(1).

In addition, under 34 CFR 99.31(a)(10) and 99.36, an educational agency or institution may disclose without prior written consent PII from an education record to appropriate parties in connection with an emergency if knowledge of the information is necessary to protect the health or safety of the student or other individuals. In making a determination about whether the sharing of H1N1 information is appropriate under this provision, an educational agency or institution may take into account the totality of the circumstances pertaining to a threat to the health of a student or other individuals. 34 CFR 99.36(c). These circumstances may include, but are not limited to, the occurrence of H1N1 at the educational agency or institution together with public health guidance about the threat posed by H1N1 and the Secretary of Health and Human Services' declaration of a public health emergency. If the educational agency or institution determines that there is an articulable and significant threat to the health or safety of a student or other individuals, it may disclose information from education records to any person whose knowledge of the information is necessary to protect the health of the student or other individuals. Id. If, in these circumstances, based on the information available at the time of the determination, there is a rational basis for the determination, the Department of Education will not substitute its judgment for that of the educational agency or institution in evaluating the circumstances and making its determination. Id. When an educational agency or institution discloses PII from an education record under the health or safety emergency exception, it must record both the articulable and significant threat to the health or safety of a student or other individuals that formed the basis for the disclosure and the parties to whom the educational agency or institution disclosed the information. 34 CFR 99.32(a)(5),

Examples of the types of situations in which the health or safety emergency exception to the general requirement of prior written consent may apply include the nonconsensual disclosure of PII from education records to a doctor if there is a student who suddenly becomes ill at school, needs emergency care, and the

**Health
Insurance
Portability and
Accountability
Act (HIPAA)**

student's parents cannot be reached or to public health authorities if a number of students at a school with H1N1 report severe illness to the school, and public health authorities seek to contact the students in order to investigate the virulence of the outbreak.

The HIPAA Privacy Rule requires entities covered by HIPAA to protect individuals' health records and other identifiable health information (known as "protected health information") by requiring appropriate safeguards to protect privacy and by setting limits and conditions on the uses and disclosures of such information without the individual's authorization. Covered entities may use or disclose protected health information only as the Privacy Rule specifically permits or requires, or if the individual who is the subject of the information (or the individual's personal representative, such as the parent of a minor) signs a HIPAA-compliant authorization form. Additionally, HIPAA gives individuals rights to their protected health information, and requires covered entities to provide individuals with a Notice of Privacy Practices and train their workforce members, including volunteers, so that they understand privacy policies and procedures.

Entities subject to HIPAA (known as "covered entities") include: health plans, health care clearinghouses, and health care providers that electronically engage in certain transactions with a health plan. Entities may determine whether they are covered by HIPAA by accessing the Department of Health and Human Services web tool at: <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/CoveredEntitycharts.pdf>

A health care provider, such as a physician practice, a hospital, or a public health department that provides health care, services, or supplies, covered by HIPAA must comply with its current HIPAA policies and procedures for the use and disclosure of protected health information in its operation of a H1N1 vaccination clinic.

The HIPAA Privacy Rule permits covered entities to use or disclose an individual's protected health information without a signed HIPAA authorization for certain purposes as specified in the Rule. Generally, covered entities must limit their uses and disclosures of protected health information to the minimum necessary for the particular purposes.

Uses and disclosures permitted without the individual's authorization include uses and disclosures for:

- Treatment, payment, and health care operations: Covered entities may share patient information with others for treatment purposes. Treatment purposes include the provision, coordination, or management of health care and related services for an individual. For example, a covered entity may share an individual's immunization records with the individual's private physician for treatment purposes.
- Public health activities: Covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability, or for the conduct of public health surveillance, public health investigations, and public health interventions. For example, a covered entity may share an individual's immunization records with an immunization registry operated by a public health department. Additional information on public health activities may be found on OCR's website (<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/publichealth/index.html>) and on CDC's web pages on Public Health and HIPAA Guidance

<http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm>).

If the use or disclosure of protected health information is not for treatment or public health activities or is not otherwise permitted under the HIPAA Privacy Rule, covered entities may use or disclose protected health information with the individual's (or his or her personal representative's) written authorization on a HIPAA-compliant authorization form. A HIPAA-compliant authorization may not be combined with a consent for treatment form. If an authorization is needed, covered entities may use their existing HIPAA-compliant authorization forms for the sharing of 2009 H1N1 vaccination information.

In most cases, the HIPAA Privacy Rule does not apply to elementary or secondary schools because the schools either: (1) are not HIPAA covered entities; or (2) are HIPAA covered entities, but maintain health information on students only in records that are by definition "education records" under the Family Educational Rights and Privacy Act (FERPA) and, therefore, are not subject to the HIPAA Privacy Rule. If a person or entity acting on behalf of a school subject to FERPA, such as a school nurse that provides services to students under contract with or otherwise under the direct control of the school, maintains student health records, these records are education records under FERPA, just as they would be if the school maintained the records directly.

However, FERPA only protects records that are held by schools or educational agencies that receive funding from the federal Department of Education. Most private schools at the elementary and secondary school levels typically do not receive funding from the U.S. Department of Education, are not subject to FERPA, and may be subject to the HIPAA Privacy Rule if they are covered entities. Additional information on the intersection of HIPAA and FERPA can be found at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf>

The above summary does not include all of the applicable requirements. The HIPAA Privacy Rule, at 45 CFR Parts 160 and 164, and the OCR website at <http://www.hhs.gov/ocr/privacy/> should be consulted.

Tools and Helpful Links

Department of Education's novel H1N1 influenza website www.ed.gov/h1n1flu

<http://www.cdc.gov/h1n1flu/schools/>

CDC's Resources for Child Care Programs, Schools, Colleges, and Universities

Note: The following are non-governmental examples of useful websites. There are many others that may be find useful.

National Association of County and City Health Officials' "School-Located Influenza Immunization School Kit" <http://www.naccho.org/toolbox/tool.cfm?id=1680>

National Association of State Boards of Education publication, "How Schools Work and How to Work with Schools"

<http://nasbe.org/hswhws/>

National Association of School Nurses, Don't get sidelined by the flu: Influenza prevention and treatment education program

<http://www.nasn.org/Default.aspx?tabid=316>

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Note: The following are examples of articles that may be useful. There are many others that may be find useful.

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