

**Arizona Novel H1N1 Influenza Vaccine Distribution Program 2009-2010  
Background Document to accompany “How to Order Novel H1N1 Influenza  
Vaccine” and “Novel H1N1 Influenza Vaccine Preregistration Form”**

**Epidemiology of novel H1N1 influenza**

Novel H1N1 influenza virus continues to cause influenza-like illness in Arizona and the US. In Arizona, the median age for novel H1N1 influenza cases is 15 years, for hospitalizations is 17 years, and for death is 49 years (as of 8/5/09) . Only 2% of cases have been in people over 65 years. Patients at increased risk of novel H1N1 influenza-related complications are similar to seasonal influenza: pregnant women, and those with asthma, COPD, diabetes, chronic cardiovascular disease, and immunocompromised individuals.

**Novel H1N1 influenza vaccine manufacturing**

Novel H1N1 vaccine is being purchased by the U.S. government from five vaccine manufacturers. Both inactivated and live attenuated novel H1N1 vaccines will be made. Inactivated vaccine will come in both single-dose syringes and in multi-dose vials. Vaccine in single-dose syringes and live-attenuated vaccine will be thimerosal-free.

**Novel H1N1 vaccine purchase and allocation**

Novel H1N1 influenza vaccine will be made available to vaccinators at no cost in increments of 100 doses. Syringes, needles, sharps containers and alcohol will also be provided, without charge. Vaccine will be allocated to states proportional to their population. Arizona Department of Health Services (ADHS) will be the ordering location for the novel H1N1 influenza vaccines allocated to Arizona.

**Planning assumptions**

The projected date of availability of novel H1N1 influenza vaccines continues to change. The most recent projection is that the first shipment of 20 million doses may be released in late September, with 100 million doses shipped in October, 80 million in November, and 80 million in December. For Arizona, that would translate into 400,000 doses at the end of September, 2 million in October, and 1.6 million in November and December.

At the present time, the assumption is that the novel H1N1 influenza vaccine will contain 15 µg of antigen, and that people will need two doses given 21 or more days apart. Clinical trials are being conducted to determine which age groups, if any, will need only one dose. The majority of vaccine will come as multidose vials but about 20% of the shipments will be thimerosal-free single-dose syringes and live attenuated vaccine.

Local health departments throughout Arizona are organizing efforts to give novel H1N1 influenza vaccine in public health clinics, in schools, and through mass vaccination clinics. However, there are not enough public health vaccinators to be the sole vaccinators to deliver novel H1N1 influenza vaccine throughout Arizona if it is to be done in a timely fashion. Therefore, nonpublic health entities such as private providers, hospitals, occupational health clinics, companies providing vaccination services, and pharmacies will need to play a large role in administering vaccine.

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### Novel H1N1 vaccine ordering

ADHS will broker the ordering and distribution of novel H1N1 vaccine in Arizona. Providers who want to give novel H1N1 vaccine to their patients will need to pre-register (see attached documents or go to <http://www.azdhs.gov/flu/h1n1/index.htm>). **There is no cost to the provider to pre-register.** Pre-registration will not obligate the provider to administer novel H1N1 influenza vaccine, but will provide ADHS with the necessary information to contact providers and arrange for shipping.

Providers who pre-register will subsequently receive instructions on how to order and reorder novel H1N1 influenza vaccine. They will also be sent a provider agreement outlining the terms and conditions of administering novel H1N1 influenza vaccine, and vaccine storage and handling requirements.

Providers who give novel H1N1 vaccine will be asked to report to ADHS on a regular basis the number of administered doses, the type of vaccine given, and whether a dose was a first or second dose. In addition, providers giving novel H1N1 vaccine to children will need to also record the novel H1N1 influenza vaccine dose in Arizona's electronic immunization registry (ASIIS).

CDC is currently writing the provider agreement. It will be similar to the Vaccines for Children agreement but simpler. Providers will need to agree not to charge for the vaccine, and to maintain proper handling and storage measures.

### Financial issues and novel H1N1 vaccine

The novel H1N1 influenza vaccine will be provided free of charge to providers. Providers can not charge recipients for the vaccine. However, providers can charge an administration fee. This could either be through fee-for-service or by billing insurance companies.

The question as to whether a provider can turn away a patient if they are unable to pay is still under discussion. Private providers will likely not be obligated to administer novel H1N1 influenza vaccine if the patient cannot pay the administration fee, but this issue has yet to be finalized as part of the provider agreement. Public health providers will not be able to turn patients away for inability to pay the fee, but they can request payment of an administration fee from insurance companies or the patient.

The Centers for Disease Control and Prevention (CDC) asked AHIP (America's Health Insurance Plans) whether insurance plans would reimburse private providers for administration and received the following answer: *"Every year health plans contribute to the seasonal flu vaccination campaign in several ways: a) Health plans communicate directly with plan sponsors and members on the current ACIP recommendations and encourage immunization; they also provide information on where to get vaccinations, and who to contact with any questions; b) Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel*

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*(A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established."*

### **Vaccine delivery**

ADHS will order vaccine when ADHS receives an order form and a signed provider agreement from the provider. **Vaccine will be shipped directly to the provider.** At times providers may only receive part of their order depending on availability of vaccine from the distributor as well as state and county prioritization guidance. In this case, providers will need to reorder more vaccine from ADHS.

Shipments will be in increments of 100 doses with a minimum shipment size of 100 doses for each type of vaccine (i.e. nasal spray, single-dose syringes, multidose vials). Providers can reorder more vaccine through ADHS as needed. Providers should develop an office communication plan to inform their patients about when novel H1N1 influenza vaccine is available in their offices and how to schedule an appointment to get it.

### **ACIP recommendations for novel H1N1 influenza vaccine target groups**

There will eventually be enough novel H1N1 vaccine to give to everyone who wants a vaccine. However, at first, the vaccine should be given to those who are most likely to get sick and have serious complication. CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that certain target groups receive the novel H1N1 influenza vaccine first. (See <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>) These recommended target groups are:

- Pregnant women
- People who live with or care for children younger than 6 months of age
- Healthcare and emergency medical services personnel
- All people from 6 months through 24 years of age
- Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.

In situations where vaccine is in limited quantities, ACIP recommends that the following groups receive the vaccine before others:

- Pregnant women
- People who live with or care for children younger than 6 months of age
- Healthcare and emergency medical services personnel with direct patient care
- Children ages 6 months through 4 years of age
- Children 5 through 18 years of age who have chronic medical conditions.

Once the demand for vaccine for the prioritized groups has been met at the local level, providers should also begin vaccinating everyone from the ages of 25 through 64 years. Finally, once vaccine demand among younger age groups has been met, providers should offer vaccination to people 65 or older.

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### **Legal protection for providers giving H1N1 influenza vaccine**

Under authority from the Public Readiness and Emergency Preparedness (PREP) Act, the Health and Human Services (HHS) Secretary has issued a declaration that gives providers immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from 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 to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures such as the novel H1N1 influenza vaccine. More information is available at [www.hhs.gov/disasters/discussion/planners/prepact/index.html](http://www.hhs.gov/disasters/discussion/planners/prepact/index.html)

### **Seasonal influenza vaccination**

Seasonal influenza vaccine will be available beginning in August or September 2009. The seasonal influenza vaccine is expected to be available earlier than the novel H1N1 vaccine, but the availability of the two vaccines is expected to overlap. The process for ordering seasonal vaccine is unchanged from previous years.

Providers should give patients the seasonal influenza vaccines **as quickly as possible** in order to free up staff time and refrigerator space for novel H1N1 influenza vaccine that will arrive later in the season. **Do not delay** seasonal influenza vaccination in hopes of getting a longer lasting immune response. Contrary to a commonly held belief, protective immunity in most people (even in the elderly) does not decline rapidly and will persist for at least a year.

### **Monitoring vaccine safety**

Vaccine safety is an important part of any vaccination program. Ongoing clinical trials are studying side effects of novel H1N1 vaccine. These side effects are expected to be similar to those from seasonal influenza vaccines. However, for any vaccine, rare side effects can only be detected by monitoring for adverse events after vaccination. This will be done through the Vaccine Adverse Event Reporting System (VAERS), and through the Vaccine Safety Datalink (VSD) that analyzes clinical data from large health maintenance organizations to identify rare events. In addition, CDC will be conducting active surveillance for Guillain-Barré Syndrome (GBS).

GBS will be looked for because the 1976 swine influenza vaccine was associated with an increased frequency of GBS (estimated at one additional case of GBS per 100,000 persons vaccinated with the 1976 swine influenza vaccine). However, it is important to inform patients that influenza virus infection itself can serve as a trigger of GBS, with the frequency of influenza-related GBS estimated at four to seven times higher than the frequency that has been estimated for influenza-vaccine-associated GBS (MMWR July 31, 2009, p.17 <http://www.cdc.gov/mmwr/PDF/rr/rr5808.pdf> )

**Call Arizona Immunization Program Office at (602) 364-3895 if you need additional information on novel H1N1 influenza vaccine pre-registering, ordering, delivery, or handling.**