LINDA LINGLE
GOVERNOR OF HAWAII

CHIYOME L. FUKINO, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

August 14, 2009

MEDICAL ADVISORY: Distribution Plans for Anticipated Novel Influenza A (H1N1) Vaccine

Dear Hawai‘i Healthcare Provider,

The first lots of the novel influenza A (H1N1) vaccine are expected to be distributed to all states this fall, possibly late September or mid-October. Many questions, such as immunogenicity, dosage, available doses, etc., remain. However, the Hawai‘i Department of Health (HDOH) would like to inform you regarding what is known and planned so that you may prepare appropriately.

The Advisory Committee on Immunization Practices has **recommended** the following groups to be the **initial targets** for novel H1N1 vaccination (http://www.cdc.gov/h1n1flu/vaccination/acip.htm):

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

HDOH plans to use multiple avenues to ensure novel H1N1 vaccine reaches these target groups, including:

- Hospital and other healthcare facilities. HDOH will distribute novel H1N1 vaccine to all Healthcare Association of Hawaii designated facilities for vaccination of all healthcare providers (*including those affiliated with a hospital facility and/or not located within it*) and their staff.
- Private primary care providers. All primary care (pediatricians, internists, family physicians, and ob/gyns) physicians may *pre-register to be a novel H1N1 vaccination provider with HDOH via a website*[1] *scheduled to go live in the next two weeks*.
  - All *primary care* physicians will be advised when the pre-registration site is accessible.
  - Physicians will be asked to provide information (e.g. medical license, specialty, contact information) to help HDOH verify identity, location, and vaccine storage capacity.
  - Novel H1N1 vaccine doses will be *supplied to authorized providers* according to HDOH specifications. Vaccination providers cannot order specific quantities or formulations as novel H1N1 vaccine doses will be supplied to states as available and pro rata from all manufacturers.
  - *Standard vaccination information* (e.g. name, vaccine type, date given, site, etc.) for each person administered vaccine *must be provided regularly to HDOH* to account for doses administered and facilitate resupply as HDOH inventory permits. All such data along with provider information will be maintained in the *Hawaii Immunization Registry*.

[1] For those providers without email or internet access, please contact us at the number provided at the end of this advisory so that other arrangements can be made.

- Community vaccinators (e.g. retail pharmacy chains, community health centers, large medical groups, colleges/universities, etc.). A separate pre-registration process will be established for these vaccination providers and will utilize the same website as for private primary care providers. Large medical groups may want to consider pre-registering as a group rather than by each individual physician.
- School-located vaccination clinics. HDOH will be conducting the 3rd year of the Stop Flu at School program, through which we provide free seasonal influenza vaccination to children in grades K-8 at 90% of all state public and private schools. We are currently querying schools to determine participation in an additional novel H1N1 vaccination clinic. These clinics would be held with an approximately 4 week interval between seasonal flu vaccination and novel H1N1 vaccination to minimize confusion and facilitate distinguishing any issues related to either vaccine.

Facts about the novel H1N1 vaccine:

- Novel H1N1 vaccine does NOT replace seasonal influenza vaccine. Seasonal influenza vaccine is necessary to prevent infection against the regular seasonal influenza strains and does not cover novel H1N1 influenza. Likewise, novel H1N1 vaccine will only cover novel H1N1 influenza and is meant to be used in addition to seasonal influenza vaccine.
- Five U.S. licensed vaccine manufacturers will produce novel H1N1 vaccine.
- Both inactivated (injectable) and live attenuated (nasal administration) will be produced. Both single and multi-dose vials will be produced. Therefore, there will be preservative-free formulations.
- It is assumed, pending completion of clinical trials, that most people (at least age 50 years and below) will require 2 novel H1N1 vaccine doses to be fully immunized and that the likely interval required will be approximately 4 weeks. However, the Centers for Disease Control and Prevention is recommending that a 2nd dose should not be reserved for those receiving the 1st dose, but that all vaccination providers should focus on vaccinating all those targeted before attempting to administer 2nd doses.
- It is assumed that seasonal flu and novel H1N1 vaccines may be coadministered; however, be advised this would make attributing any potential effects to a particular vaccine difficult.
- Further understanding regarding the vaccine is pending completion of clinical trials which have just been initiated.
- All novel H1N1 vaccine doses, needles, syringes, alcohol swabs, and sharps containers will be provided to states at no cost. Therefore, providers may not charge patients for these supplies.
- It is likely that private providers will be able to charge to insurance providers an administrative fee for those vaccinees with insurance. However, confirmation is pending as the process is being worked out.

If you have questions about the process for novel H1N1 vaccine distribution in Hawaii, you may send inquiries to h1n1vax@doh.hawaii.gov, or, if you do not have email access, you may contact Lisa Mendez, Immunization Branch Chief, at (808) 586-8300.

We appreciate the partnership of the medical community in preventing all influenza infections and protecting the health of the people of Hawai‘i.

Sincerely,

Sarah Y. Park, MD, FAAP
State Epidemiologist
Hawaii Department of Health