



Flu Vaccine Planning Kit for the Healthcare Supply Chain

(2009-2010)

Last Updated 11/11/09

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About Us



The Flu Vaccine Business Practices Initiative is a voluntary group of flu vaccine distributors, manufacturers, and influenza stakeholders who are committed to working with the Centers for Disease Control and Prevention to ensure that seasonal flu vaccine is efficiently distributed. The goal of the Initiative is to educate and inform audiences about the flu vaccine supply chain.

The Flu Initiative is formally supported by the CDC/AMA-led National Influenza Vaccine Summit (Executive Committee).

The Flu Initiative was formed in 2006 by seasonal flu vaccine distributors to promote flu vaccine supply transparency and education. The Flu Initiative and its Web site www.FluSupplyNews.com is administered by the Health Industry Distributors Association (HIDA), www.HIDA.org.

Key Questions

How are seasonal flu vaccine and other products allocated during times of scarcity or high demand?

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Seasonal and H1N1 Flu

How Medical Products Are Distributed During Times of Scarcity or High Demand

A Primer on Order Allocation in the Medical Materials Supply Chain

**Source: Medical Materials Coordinating Group (MMCG)
September, 2009**

Order allocation as used in the medical materials supply chain is a vehicle for control of how products are distributed when supplies are scarce or when ordering volumes significantly exceed historic norms.

When used in the distributor's locations, it usually indicates that the manufacturers are not shipping full replacement orders or that the customers for that distributor are ordering quantities that are exceptionally larger than normal. Filling complete orders on a first in, first out basis would threaten the ability of the distributor to meet other customers' full or partial demands.

Distributors use allocation to preserve business relationships by assuring that no single source can deplete enough supply to threaten the ability of the distributor to at least partially satisfy other customers that might use the same source and product. Allocation is simply a distribution limiter that allows orders to be filled in proportion to the previous histories of existing customers. It can also be an allocation of inventory on hand as a percentage of traditional volume if the on hand stock is lower than traditional levels.

In either case, customers that are not existing customers, those who have not ordered from that distributor in recent periods, are not shipped product unless surplus product exists at the distribution center. New customers have no order history; hence their orders are generally not filled at all.

Once distributors go to an allocation method of filling orders, there is no ability on the part of a hospital or health system to seek alternative distributors. In those cases, the healthcare providers would need to order an alternative product, likely from the same distributor as the original product.

With respect to the N95 mask, changing to an alternative product would mean that healthcare providers would have to fit test the N95 mask in accordance with NIOSH and OSHA regulations. As a result, the providers would have to order sufficient quantities to conduct the fit testing of the individuals that would be using the alternate brand of N95 respirator. In the case of the manufacturers, allocation is a way of limiting distribution to preserve their customer base as well. Some manufacturers will distribute directly to a facility that is a member of a health system, and they may also distribute through external distribution channels for subsequent distribution to the health system's facilities. In either case, they will again limit the amount that is distributed so that they do not jeopardize their relationships with either their hospital consumers or their distribution channel partners. They will partially fill orders until manufacturing can again meet the demand.

In some cases, manufacturers will only distribute their product to either the health care providers or to the distribution network but not to both. These manufacturers will use the same strategy to preserve their existing customer relationships by limiting order fulfillment.

In summary, the order allocation strategy can be employed when demand far exceeds past history or when supply becomes scarce or limited. Allocation assures that existing customers will get some part of their needed orders but not to sacrifice the ability to satisfy other customers.

This paper was prepared by the Medical Materials Coordinating Group (MMCG), a component of the Healthcare and Public Health Sector Coordinating Council (HPH-SCC). Established under the National Infrastructure Protection Plan, the HPH-SCC is a self-organized, self-run, and self-governed organization of private sector stakeholders in healthcare and public health critical infrastructure protection. The HPH-SCC enables healthcare and public health sector owners and operators to interact on a wide range of sector-specific strategies, policies, activities, and issues.

MMCG Membership

Advanced Medical Technology Association (AdvaMed)
American Medical Depot
Association for Healthcare Resource & Materials Management (AHRMM)
Baxter Healthcare Corporation
Cardinal Health
Health Industry Distributors Association (HIDA)
Henry Schein, Inc.
Medline Industries, Inc.
Owens & Minor, Inc.
Regional Medical Center
Terumo Medical Corporation
Tuomey Healthcare System
Universal Hospital Services

The Medical Materials Coordinating Group (MMCG) is a subgroup of the U.S. Department of Homeland Security's [Healthcare Sector Coordinating Council](#) (HSCC). The MMCG is comprised of 15 owner-operator and association members that represent the medical products supply chain, including manufacturers, consolidators, distributors, and maintenance and repair. The HSCC and MMCG are recognized by the U.S. Department of Homeland Security and other federal agencies as the initial point of contact within healthcare's private industry for critical infrastructure protection, preparedness and response purposes.

For more information, contact the Health Industry Distributors Association at 703-549-4432 or e-mail Michael@HIDA.org or Frazier@HIDA.org.

H1N1 Flu

H1N1 Influenza Vaccine Distribution: *Recent CDC Guidance*

The document is presented by the Health Industry Distributors Association and the Flu Vaccine Business Practices Initiative (www.FluSupplyNew.com). The information presented is collected from the following sources:

- The National Influenza Vaccine Summit – Aug. 18, 2009 Conference Call
- *H1N1 Vaccine Distribution*. HDMA H1N1 Influenza Preparedness Planning Workshop. Dr. Tom Shimabukuro, Immunization Services Division of the National Center for Immunization and Respiratory Diseases, U.S. Centers for Disease Control and Prevention. Aug. 20, 2009.
- *CDC Novel H1N1 Vaccination Planning Q&A*. U.S. Centers for Disease Control and Prevention. Aug. 10, 2009. [Http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm](http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm)
- The U.S. Centers for Disease Control and Prevention at www.cdc.gov/flu

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Background

Novel H1N1 (also referred to as “swine flu”) is a new influenza virus causing illness in people. This new virus was first detected in people in the United States in April 2009. The virus is spreading from person-to-person worldwide, probably in much the same way that regular seasonal influenza viruses spread. On June 11, 2009, the [World Health Organization](#) (WHO) signaled that a pandemic of novel H1N1 flu was underway.

As time passes, health experts are acquiring new information about the H1N1 virus and officials are updating their preparedness plans and strategies. As of August 2009, the CDC reports that:

- The H1N1 epidemiologic picture indicates an age distribution that is different from seasonal flu in that H1N1 flu has caused greater disease burden in people younger than 25 years of age versus older people. To date, the CDC states that the disease has not been severe and economic/social disruption may not be as extensive as first thought during initial planning projections. Health officials are watching to see how the H1N1 virus may evolve during the 2009-2010 flu season.
- There is the potential for confluence seasonal and pandemic flu vaccination during the 2009-2010 influenza season.

H1N1 Flu Campaign:

- **Approximately 195 million doses of H1N1 vaccine will be purchased by the U.S. government**
- **H1N1 vaccine will be distributed to ~90,000 sites**
- **Early indications show that one dose of H1N1 vaccine may be adequate for patients age 10 and older; 2 doses of H1N1 vaccine are advised for children younger than age 10. Clinical trials are ongoing to determine final dosage recommendations. (Initially 2 doses were assumed for all patients.)**

Seasonal Flu Campaign

- **Production of ~115 million doses anticipated for 2009-2010 seasonal flu vaccination**

Source: CDC (9/18/09)

How Centralized H1N1 Vaccine Distribution Will Work

H1N1 vaccine will be made available to providers and patients for free. The Centers for Medicare and Medicaid Services will be offering [reimbursement](#) to providers for the administration of H1N1 vaccine.

The government will utilize a centralized distribution system with one single vaccine/medical products distributor (similar to the current seasonal Vaccines for Children or VFC program). This centralized, VFC-type distribution infrastructure will be used for the duration of the H1N1 campaign, according to current reports from CDC officials. However, new distribution centers and products will be included in the H1N1 process (ex. ancillary products and supplies related to flu vaccine administration such as needles, syringes, etc.).

Several key steps will be involved in centralized distribution:

1. Registered H1N1 providers will request vaccine through their state health departments. **Each state will get a pro rata allocation of vaccine and each state will designate/allocate that vaccine accordingly.**

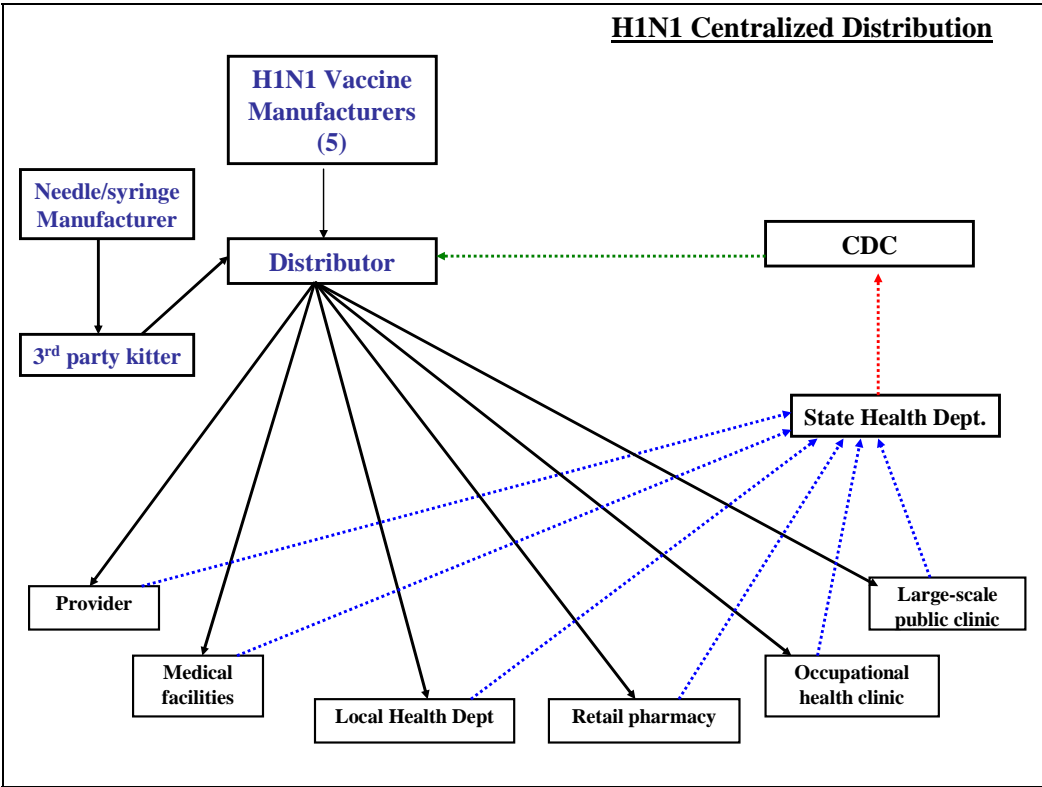
Because the minimum shipment size for H1N1 vaccine (100 doses) may exceed the space that some providers have available, the states may determine a storage location to warehouse the vaccine so that it can be parsed out to smaller providers in an order size that they can accommodate.

[Note: Providers must be enrolled/registered with their state health departments to participate in H1N1 vaccination administration. Every state will post registration information online and this data will also be [consolidated by the CDC.](#)]

2. State health departments will serve as a clearinghouse for vaccine orders and will then forward those orders to the CDC.
3. The CDC will send vaccine orders and ship-to locations to its central distributor, which will funnel and track all H1N1 orders.
4. The central distributor will send vaccine (and related kits of ancillary supplies) to CDC-specified sites/providers.

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The diagram below illustrates how centralized H1N1 distribution will work:



Data Source: *H1N1 Vaccine Distribution*. Shimabukuro, Tom. U.S. Centers for Disease Control and Prevention. Aug. 20, 2009.



H1N1 Vaccination Planning Q&A *CDC Guidance –August 2009*

This information is authored and provided by the Centers for Disease Control and Prevention (CDC). The original document is located at <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>

Vaccine Distribution

Q. When will the decision to administer vaccine be made?

A. For planning purposes, it should be assumed that vaccine will be administered beginning in the fall.

Q. When will vaccine shipping begin?

A. Planners should assume shipping of vaccine will begin mid-October, although there is a possibility that some vaccine will be available for shipping starting late September.

Q. How many manufacturers are producing vaccine?

A. Five manufacturers are producing vaccine for the U.S.: Sanofi Pasteur, Novartis, GSK, MedImmune and CSL.

Q. How much vaccine can be expected to be available for shipping when shipping begins?

A. Planners should use the following scenarios: In the first scenario, approximately 120 million doses will be released beginning around mid-October over a 4 week period, followed by approximately 20 million doses per week (or 80 million doses per month) thereafter. In the second one, up to 20 million doses of vaccine will be released beginning late September, followed by approximately 20 million doses per week (or 80 million doses per month) thereafter. Please monitor www.CDC.gov/flu for updates on this timeline.

Q. How will vaccine be shipped to projects areas (CDC Public Health Emergency Preparedness grantees)?

A. Vaccine will be shipped to clinics, offices, health departments, and other project area-designated sites which may include a mix of public health and private sector sites via centralized distribution. This is the same process that is used to ship vaccines for the childhood immunization program to immunization providers. CDC's centralized distribution mechanism will be substantially enhanced to provide capacity for this activity in addition to shipping of other vaccines.

Q. Will project areas (CDC Public Health Emergency Preparedness grantees) be able to limit the amount of vaccine they receive?

A. Yes, project areas will be able to determine what proportion of their allocation they wish to receive.

Q. How frequently will vaccine shipments arrive?

A. As details of distribution are finalized, CDC will communicate with states about the anticipated time period between placing vaccine orders and receiving shipments.

Q. How many sites can be designated as vaccine receiving sites?

A. One of the key benefits of using a centralized, third party distributor to support H1N1 vaccine distribution is that it allows distribution of doses to a much larger number of providers sites than would be feasible with direct manufacturer distribution. Thus, we will be able to serve a significantly larger provider base than the original state ship to sites, and are planning to be able to accommodate more providers than are currently served by the VFC program. More information, including any limitations in the number of vaccine receiving sites, will be shared with state planners as soon as it becomes available.

Q. Will vaccine be in multi-dose vials?

A. The majority of vaccine will be in multi-dose vials, the remainder in single dose syringes or nasal sprayers. The aim is to have enough vaccine in single dose syringes (i.e. preservative free) for young children and pregnant women.

Vaccine Allocation

Q. How will vaccine be allocated among project areas (the CDC PHEP grantees)?

A. Vaccine will be allocated to each project area in proportion to its population (pro rata).

Q. Will there be a separate allocation for active duty DOD?

A. Yes, there will be a separate allocation for active duty DoD. It is not included in the project area allocations.

Q. Will there be a separate allocation for DoD dependants, retirees and civilian employees?

A. There is no separate allocation for these groups. Military facilities may be willing to vaccinate these groups, but will need to be allocated vaccine for these populations by the project areas.

Q. Will there be a separate vaccine allocation for IHS-served populations and other tribal communities?

A. There will be no separate allocation. States and local areas need to work with their tribal populations to ensure access to vaccine.

Ancillary Supplies

Q. Which ancillary supplies will be provided with vaccine?

A. HHS will provide needles, syringes, sharps containers and alcohol swabs.

Q. How will ancillary supplies be distributed?

A. Ancillary supplies will be distributed to the same project area-designated sites as vaccine. Plans for ensuring the distribution of these products are currently being developed.

Vaccine Administration

Q. Will two doses of vaccine be required?

A. This will not be known until the late summer- early fall, once clinical trials are completed. For planning purposes, planners should assume that two doses will be needed.

Q. What will be the recommended interval between the first and second dose?

A. This will not be known until clinical trials are complete. For planning purposes, planners should assume 21-28 days between the first and second vaccination.

Q. How much Thimerosal-free vaccine will be available?

A. It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women.

Q. Will there be federal requirements to recall persons for their second dose, if a second dose is needed?

A. There will be no federal requirement to send out recall notices. Providing information on second dose at the time of the first dose, as well as using the media to disseminate this message will be the primary means of educating persons about who needs a second dose administered.

Q. Will it be necessary for the first and second dose to be the same product?

A. Ideally, first and second doses would be from the same product. However, practical considerations make this difficult to implement. Planners should assume they will be interchangeable.

Q. Can seasonal vaccine and novel H1N1 vaccine be administered at the same time?

A. Clinical trials are exploring this question. It is anticipated that seasonal vaccine and novel H1N1 vaccines may be administered together.

Q. Will vaccine be adjuvanted?

A. It is unlikely H1N1 vaccine will be adjuvanted. Definitive information will be available once clinical trial data are available.

Q. If vaccine is adjuvanted, how will it be formulated?

A. Formulation will vary by provider. For Novartis, vaccine may be preformulated with adjuvant. For CSL, GSK and Sanofi Pasteur, mixing of vaccine and adjuvant at the site of administration will be necessary. Specific information on storage requirements and procedures for mixing vaccine and adjuvant will be provided by CDC. MedImmune vaccine will not be adjuvanted.

Q. Will the vaccine be administered under EUA (Emergency Use Authorization)?

A. EUA will not be used for unadjuvanted vaccine if FDA licenses the vaccine under the current BLA (Biologics License Application) as a strain change.

Q. For whom will novel H1N1 vaccine be recommended?

A. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) met on July 29th to develop recommendations on who should receive the novel 2009-H1N1 vaccine when it becomes available, and to determine which groups of the population should be prioritized if the vaccine is initially available in extremely limited quantities. The committee recommended that vaccination efforts initially focus on 5 target groups: vaccination for pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months through 24 years, and people ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems. We do not expect that there will be a shortage of novel H1N1 vaccine, but flu vaccine availability and demand can be unpredictable and there is some possibility that initially, the vaccine will be available in limited quantities. So, the ACIP also made recommendations regarding which people within the groups listed above should be prioritized if the vaccine is initially available in extremely limited quantities. For more information see the CDC press release [CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1](#). Once the demand for vaccine for the prioritized groups has been met at the local level, programs and providers should also begin vaccinating everyone from the ages of 25 through 64 years. Current studies indicate that the risk for infection among persons age 65 or older is less than the risk for younger age groups. However, once vaccine demand among younger age groups has been met, programs and providers should offer vaccination to people 65 or older. (see <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>)

Q. Will there be flexibility in how states implement the recommendations?

A. The ACIP recommendations leave room for flexibility at the local level depending on the local vaccine supply situation.

Q. Given the potential for large amounts of vaccine available during the first month of vaccine shipments, are priority groups needed?

A. It is not expected that there will be a shortage of novel H1N1 vaccine, but availability and demand can be unpredictable, and there is some possibility that initially the vaccine will be available in limited quantities and priority groups may be needed.

Q. Will there be requirements regarding documentation of priority group membership?

A. There will be no federal requirements for vaccinators to require documentation of priority group status such as a doctor's note documenting pregnancy or risk status.

Doses Administered Monitoring

Q. What are the minimum data elements required by CDC?

A. Minimum data requirements include age group, 1st or 2nd dose, date of vaccination, and state.

Pneumococcal Vaccination

Q. Are there any changes in recommendations for pneumococcal vaccines?

A. The ACIP recommends that persons recommended for pneumococcal vaccine receive it in light of the potential for increased risk of pneumococcal disease associated with influenza. There are at present no recommendations to give pneumococcal vaccine to groups for whom it is not currently recommended. ACIP will revisit this question over the summer as epidemiologic data from the Southern hemisphere influenza season and from the U.S. become available.

Questions?

The CDC can be reached via phone 24 hours a day at 800-CDC-INFO (800-232-4636), via e-mail at cdcinfo@cdc.gov, or via mail 1600 Clifton Road, Atlanta, GA 30333.

State/Jurisdiction Web sites for Healthcare Providers Interested in Administering H1N1 Vaccine

United States

Alabama

<https://dph.state.al.us/order/>

Alaska

<https://vactrak.alaska.gov/iweb/>

Arizona

http://www.surveymonkey.com/s.aspx?sm=W0shQr3nUyQM8hIAjitxww_3d_3d

Arkansas

<http://www.healtharkansas.com/news/swineflu-resources.html>

California

<http://www.calpanflu.org/>

Colorado

<http://www.cdphe.state.co.us/epr/h1n1.html>

Connecticut

<http://www.ct.gov/ctfluwatch/cwp/view.asp?a=2533&q=444978>

Delaware

<http://dhss.delaware.gov/dhss/dph/dpc/files/h1n1providerpreregform.pdf>

District of Columbia

<http://newsroom.dc.gov/show.aspx/agency/doh/section/2/release/17978>

Florida

<https://www.flshots.com/flshots/signin.csp>

Georgia

<http://health.state.ga.us/h1n1flu/>

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Hawaii

<http://h1n1vax.doh.hawaii.gov/welcome.html>

Idaho*

<http://www.healthandwelfare.idaho.gov/Health/PanFluHome/H1N1/tabid/892/Default.aspx>

Illinois

http://www.idph.state.il.us/h1n1_flu/sf_healthcare.htm

Indiana*

<http://www.in.gov/flu/>

Iowa

<http://www.idph.state.ia.us/h1n1/vaccine.asp>

Kansas

https://www.dhe.state.ks.us/surveys/private_provider_sign-up.htm

Kentucky

<https://khelps.chfs.ky.gov/VolunteerMobilizer/>

Louisiana

https://linkweb.oph.dhh.louisiana.gov/linkweb/la_h1n1_registration.jsp

Maine

<http://www.maine.gov/dhhs/boh/maineflu/h1n1/provider-agreement-2009-2010.shtml>

Maryland

<http://dhmh.state.md.us/swineflu/index.html>

Massachusetts

<http://www.mass.gov/dph/h1n1registration>

Michigan

http://www.michigan.gov/mdch/0,1607,7-132-2940_2955_22779_53388-214187--,00.html

Minnesota

<http://www.health.state.mn.us/divs/idepc/diseases/flu/h1n1/vaccine/ordering.html>

Mississippi

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http://www.healthmys.com/msdhsite/_static/resources/3330.pdf

Missouri

http://www.dhss.mo.gov/BT_Response/MedProfs.html

Montana*

<http://www.dphhs.mt.gov/influenza/healthcare.shtml>

Nebraska

<http://dhhs.ne.gov/H1N1flu/clinicians.htm>

Nevada

http://www.flu.nv.gov/HCP_ProviderPre_Reg.htm

New Hampshire

http://www.dhhs.nh.gov/DHHS/DHHS_SITE/swineflu.htm

New Jersey

<http://njiis.nj.gov/njiis/html/h1n1home.html>

New Mexico

<http://www.health.state.nm.us/H1N1/provider.shtml>

New York

<https://hcsteamwork1.health.state.ny.us/pub>

North Carolina

<http://www.immunizenc.com/Providers.htm>

North Dakota*

<http://www.ndflu.com/h1n1/>

Ohio

<http://h1n1vaccine.odh.ohio.gov/>

Oklahoma

<http://osiis.health.ok.gov/>

Oregon

<http://www.oregon.gov/DHS/ph/acd/flu/h1n1flu-subcommittee.shtml>

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Pennsylvania

<http://www.dsf.health.state.pa.us/health/cwp/view.asp?q=242182>

Rhode Island

<http://pandemic.health.ri.gov/h1n1/action/register>

South Carolina

<http://www.scdhec.gov/flu/swine-flu.htm>

South Dakota

<http://doh.sd.gov/H1N1/default.aspx>

Tennessee

<http://health.state.tn.us/twis/>

Texas

<http://www.dshs.state.tx.us/txflu/H1N1VaccineRegiInstructions.pdf>

Utah

<http://health.utah.gov/epi/h1n1flu/groups/clinician.html>

Vermont

<http://www.healthvermont.gov/panflu/hcprovider.aspx>

Virginia

<http://www.vdh.virginia.gov/epidemiology/immunization/h1n1prereg.htm>

Washington

<http://www.doh.wa.gov/swineflu/h1n1reg.htm>

West Virginia

<http://www.wvdep.org/Home/HotTopicSwineInfluenza/tabid/1856/default.aspx>

Wisconsin

<http://pandemic.wisconsin.gov/category.asp?linkcatid=3147&linkid=903&locid=106>

Wyoming

<http://www.health.wyo.gov/familyhealth/immunization/SwineFlu2009.html>

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Commonwealths & Territories

American Samoa*

<http://americansamoa.gov/index.htm>

Federated States of Micronesia*

<http://www.fsmgov.org/>

Guam*

<http://www.dphss.guam.gov/H1N1/flu.htm>

Northern Marianas*

<http://mymarianas.com/html/display.cfm?sid=1009>

Puerto Rico*

<http://welcome.topuertorico.org/government.shtml>

Virgin Islands*

<http://www.healthvi.org/>

*As of 9/18/09 these sites do not have information for providers to obtain the H1N1 vaccine.

For additional state contact information, visit the CDC state contact list at

<http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm>