

**2009 H1N1 Influenza Monovalent Vaccine
Vaccine Provider Agreement**

Applicant: _____

License: _____

H1N1 Immunization Provider Names and applicable medical/nursing licensure numbers

of _____
Facility Name

Address of primary facility

Address for receipt of vaccine

Your participation in the 2009 H1N1 Influenza monovalent vaccine vaccination effort is greatly appreciated as a vital service that will protect individuals and the public against 2009 H1N1 influenza. The 2009 H1N1 Influenza monovalent vaccine has been purchased by the federal government as a means of protecting the public against 2009 H1N1 Influenza. It is being made available to immunization providers working in partnership with state and local public health departments to vaccinate individuals for whom the vaccine is recommended. This Provider Agreement specifies the conditions of participation in the 2009 H1N1 Influenza monovalent vaccine vaccination effort in the U.S. and must be signed and submitted to the immunization program prior to receipt of the vaccine.

The immunization provider agrees to:

1. Administer the 2009 H1N1 Influenza monovalent vaccine according to the recommendations of CDC's Advisory Committee on Immunization Practices as adopted by the Centers for Disease Control and Prevention.
2. Store and handle the vaccine in accordance with the package insert provided with the vaccine including in compliance with cold chain requirements.
3. Provide a current Vaccine Information Statement (VIS) to each individual before vaccination, and answer questions about the benefits and risks of vaccination, including different indications for live versus inactivated vaccines.
4. Record in the patient's medical record or in an office log the date of administration, the site of administration, the vaccine type and lot number, and the name of the immunization provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination.
5. Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967, <http://vaers.hhs.gov/contact.htm>).

In addition, the provider:

6. Can not charge patients, health insurance plans, or other third party payers for the vaccine, the syringes or the needles as these are provided at no cost to the provider. The provider/facility is also prohibited from selling H1N1 vaccine, syringes or needles.
7. May charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare vaccine administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed

the state Medicaid administration fee.

8. May either administer the 2009 H1N1 Influenza monovalent vaccine for free to individuals who cannot afford the administration fee, or refer these individuals to a health department clinic or affiliated public health provider for vaccination.
9. Must report the number of doses of 2009 H1N1 Influenza monovalent vaccine administered to individuals as requested by the state or local health department.
10. Must report to the state health department the number of doses of vaccine that were not able to be used because the vaccine expiration date was exceeded or the vaccine was wasted for other reasons. These doses must be disposed of in accordance with Rule 64E-16, F.A.C. (Biomedical Waste).
11. Are strongly encouraged to provide an immunization record card to the vaccine recipient or parent/guardian to provide a record of vaccination, to serve as an information source if a Vaccine Adverse Event Reporting System report is needed, and to serve as a reminder of the need for a second dose of vaccine (if necessary). Immunization cards will be included in each shipment of vaccine.
12. U.S. Code - Public Readiness and Emergency Preparedness Act

[42 USC Sec. 247d – 6d](#)

[42 USC Sec. 247d – 6e](#)

Note: The PREP Act immunizes “covered persons” from a wide list of tort claims (does not create a long list of immunized persons). The immunity is immunity from suit – much stronger than the sovereign immunity under Florida Statutes.

The definition of a “covered person” is broad. Covered persons include the federal government, manufacturers, distributors, program planners, entities such as hospitals, and people such as physicians qualified to administer the countermeasure. 42 U.S.C. § 247d-6d(i)(7)-(7)(A)(ii). Therefore, physicians, nurses and anyone else who administers the vaccine at the direction of a physician are “covered persons” for purposes of Federal PREP Act immunity.

“[The] covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure”. 42 U.S.C. § 247d-6d(a)(1).

Receipt of H1N1 vaccine shall constitute acceptance of the terms of this agreement.