

## **Program Element 04: Public Health Response to H1N1 Influenza Vaccination Program**

1. **Description.** Funds provided under this Agreement for this Program Element may only be used, in accordance with and subject to the requirements and limitations set forth below to operate a vaccination program to respond to the H1N1 influenza pandemic. The Centers for Disease Control and Prevention (CDC) released guidelines to DHS and local health officials with planning strategies for administering H1N1 vaccines. LPHA will schedule, implement and provide follow up for vaccination clinics to provide efficient and prompt distribution of H1N1 vaccination to persons residing in LPHA service area. LPHA have three options for providing services under this Agreement. LPHA may choose one or a combination of the following three options:
  - a. **Redistribution.** LPHA may utilize the H1N1 Order Tracking Database to supply local private and public partner organizations living within LPHA service area with vaccine allocated to LPHA.
  - b. **Implement H1N1 Vaccination Clinics.** LPHA may utilize H1N1 vaccine allocated to them via the CDC, as reflected on the H1N1 Order Tracking Database, to plan and implement immunization clinics for public clients residing or visiting the LPHA service area.
  - c. **DHS Mass Vaccination Contract.** LPHA may access the services of Contractor Agencies via the state-wide DHS Mass Vaccination Contract. LPHA must abide by terms outlined in Section 4 of this document, “Responsibilities Regarding Mass Vaccinator Contracted Services”.
2. **Definitions Specific to H1N1 Influenza Vaccination Program.**

**CDC:** U. S. Department of Health and Human Services, Centers for Disease Control and Prevention.

**DHS:** Oregon Department of Human Services, Public Health Division

**H1N1 LPHA Contact:** This is an LPHA staff that has been designated as the primary point of contact for DHS regarding H1N1.

**H1N1 Order Tracking Database:** This is an internet database created and maintained by the Oregon DHS Public Health Immunization Program. It is used to display current allocations of H1N1 vaccine to LPHA. The database reflects current allocations and allows LPHA to designate recipients of H1N1 vaccine. The database is not publicly accessible and requires pre-registration to view.

**H1N1 Pandemic Influenza:** Pandemic H1N1 is a novel strain of Influenza type “A” virus first identified in April 2009. It causes illness symptoms and severity that are similar to those resulting from seasonal flu infection. However, because it is a new virus, very few people have immunity, and, as a result many may become ill with this infection.

**Incident Command System Standard:** The National Incident Management System's standard for facilities, equipment, personnel, procedures, and communications operating within a common organizational structure, to perform domestic incident management activities in response to incidents, such as explosions, bioterrorism attacks, chemical releases, earthquakes, and tsunamis, which have significant public health impact.

**Mass:** A large, but non-specific amount or number

**National Incident Management System (NIMS):** The Federal Homeland Security Administration's system for integrating effective practices in emergency preparedness and response into a comprehensive national framework for incident management. The NIMS enables emergency responders at all levels and in different disciplines to effectively manage incidents no matter what the cause, size or complexity. More information can be viewed at: <http://www.fema.gov/emergency/nims/index.shtm>

**Public Health Emergency Response (PHER) Grant:** Funding provided by U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) for Public Health Emergency Response (PHER). The purpose of the grant is to support and enhance the DHS and local public health infrastructure that is critical to public health preparedness and response.

**VAR:** Vaccine Administration Record. Record of vaccine administration which provides detailed information on the type of vaccine provided.

**VIR:** Vaccine Information Record. Printed informational sheets for each type of vaccine licensed in United DHSs. According to the National Vaccine Safety Act, these forms are Federally-mandated to be provided to clients prior to being vaccinated. Available at: [http://www.immunize.org/vis/vis\\_alpha.asp](http://www.immunize.org/vis/vis_alpha.asp)

3. **Procedural and Operational Requirements.** All of LPHA's H1N1 influenza vaccination services and activities supported in whole or in part with funds provided under this Agreement shall be delivered or conducted in accordance with the following requirements:
  - a. **Non-Supplantation.** Funds provided under this Agreement for this Program Element shall not be used to supplant DHS, local, other non-federal, or other federal funds.
  - b. **Audit Requirements.** In accordance with federal guidance, each entity receiving funds shall audit its expenditures of PHER funding. Such audits shall be conducted by an entity independent of DHS and in accordance with the federal Office of Management and Budget Circular A-133. Audit reports shall be sent to the Department, who will provide them to the CDC. Failure to conduct an audit or expenditures made not in accordance with PHER cooperative agreement guidance and grants management policy may result in a requirement to repay funds to the federal treasury or the withholding of funds.
  - c. LPHA's shall either provide or ensure the provision of immunization clinics to members of the public at designated vaccination clinics within the LPHA service area. LPHA shall supply clinical, administrative, and logistical personnel, make facilities arrangements and publicize for requested vaccination clinics within LPHA service area. The proposed clinics

may be held at a variety of community settings, to include: schools, health facilities, airports and bus terminals, public gathering places like auditoriums, and other locations deemed appropriate by LPHA.

- d. LPHA shall provide services and comply with all requirements identified herein, shall abide by all policies and procedures established by DHS and all other state and federal laws, rules, and regulations, including priority groups identified by CDC and DHS guidelines.
- e. LPHA shall comply with all requirements outlined in Appendix A “ Oregon H1N1 Provider Agreement“ of this Program Element, including temperature monitoring and submission of doses administered to the ALERT Immunization Information System.
- f. LPHA shall administer H1N1 vaccines in all available presentations for all appropriate ages, as supplied by DHS, including the nasal spray.
- g. LPHA shall be responsible to report site locations, dates, schedules, and other pertinent details. These reports shall be in a format provided by DHS and shall be at least weekly or more frequently as requested by DHS or if there are any changes.
- h. LPHA shall appoint a single staff, the LPHA H1N1 Contact, to coordinate H1N1 campaign and vaccination efforts with DHS and with the DHS Mass Vaccinator Contract Agencies (if LPHA choose to use that option). This LPHA staff will have an appropriate staff designated as an alternate, to provide for business continuity.
- i. LPHA shall maintain and update the H1N1 Order Tracking Database when shipping doses from allocation of H1N1 vaccine to a registered provider. No vaccine will be shipped to unregistered providers within the LPHA boundaries. Doses of vaccine being distributed beyond LPHA boundaries must remain within the boundaries of the DHS of Oregon. LPHA that wishes to distribute H1N1 vaccine beyond LPHA boundaries will notify the H1N1 Research Analyst of the intended recipient and number of doses at: 971-673-0316 or [scott.r.jeffries@DHS.state.or.us](mailto:scott.r.jeffries@DHS.state.or.us) .

#### **4. LPHA Responsibilities Regarding DHS Mass Vaccinator Contracted Services**

- a. LPHA shall be responsible to ensure arrival of vaccine, clinical supplies, and required forms at the designated location in a timely manner. This may include escort or security protection of vehicles transporting vaccine or clinical supplies from Public Provider or ship-site to location of the scheduled community immunization clinics.
- b. LPHA shall be responsible for acquiring a location, advertisement of the clinic date and time, contact with local media or government officials, securing the appropriate contracts, permits, and local permissions to implement a scheduled community immunization clinic in a non-disruptive and orderly fashion. LPHA is responsible for ensuring information about clinics provided by mass vaccinators in the LPHA service area is included in reports provided to DHS about where the public can receive H1N1 vaccination for posting on the DHS website.
- c. LPHA shall transport staff, supplies, forms, signage and any necessary equipment to and from each requested mass DHS vaccination contract clinic.

- d. LPHA shall submit to DHS a confirmation that Contractor invoice is appropriate to pay the Contractor within nine calendar days of receiving completed Dose Batch Reporting form from Contractor. Request for payment will include event details (location, time, date), and an assurance that Contractor provided services to the number of clients reflected on the invoice and returned any surplus vaccine and supplies. Reports will be used to reconcile dose administration data with dose inventory data. Discrepancies will be resolved to the satisfaction of DHS.
  - e. This report shall be forwarded to DHS with all completed, original client Vaccine Administration Records (VAR), unless LPHA prefers an alternate DHS approved method of dose reporting to the ALERT Information System (such as online entry, Barcode entry, or IRIS data entry methods) and plans to retain their own original client VAR forms rather than use the scannable VAR form.
5. **LPHA Restrictions.** The LPHA shall comply with the following restrictions, unless granted a written and specific exception by DHS.
- a. LPHA may not use these funds to establish an in-house billing system, however the funds maybe used to contract with a third party billing firm.
  - b. LPHA using a DHS Mass Vaccination Contractor Agency (under that option) may solicit fee donations from clients if the following guidelines are followed:
    - i. Client may not be solicited or informed until after immunization services are rendered.
    - ii. Advertisement and publicity may not include solicitations for donations.
    - iii. Solicitation is to be by provision of a pre-addressed envelope for clients to mail check or money order directly to the LPHA.
    - iv. Under no circumstance will LPHA or Contractor receive donations directly from clients, only donations mailed to LPHA may be accepted.
    - v. Solicitation must clearly DHS that it is an optional donation. Fee, Administration Fee, Charge, or similar verbiage are not to be used.
    - vi. Mass Vaccination Contractor Agency will not accept or solicit donations from clients, but may provide the pre-printed envelopes for the LPHA whose service area contains the clinic.
6. **Billing, Payment, and Administrative Fees.** Billing, Payment and Administrative Fees are governed by federal guidelines viewable at:  
<http://www.oregon.gov/DHS/ph/imm/docs/H1N1PlanQA.pdf>
- a. LPHA or Mass Vaccinator Contractor operating under LPHA may screen for insurance eligibility of clients and bill a third party payor for a vaccine administration fee provided at community immunization clinic for those clients whose coverage can be billed by the LPHA. In this case, the administration fee billed to a third party payor shall not exceed the current established administration fee for the locality and coverage situation the dose was administered in:

- i.** For clients who are privately insured by a 3<sup>rd</sup> party payor or covered by Medicare, \$20.96 in Portland, \$19.68 other localities in Oregon
  - ii.** For clients who are covered by Medicaid, \$15.58
  - iii.** For clients who are covered by another 3<sup>rd</sup> party payor, administration fee may only charge the 'usual and customary' fee that LPHA bills for seasonal influenza vaccine. Clients whose 3<sup>rd</sup> party payor or private insurance rejects the claim may NOT be sent a bill.
  
- b.** When accessing Contractor services under the DHS Mass Vaccination Contract, LPHA shall provide DHS a roster of clients by name, date of service, and date of birth. This roster will differentiate between clients whose insurance was billed and clients who were not able to be billed or who did not have coverage to bill. LPHA shall submit all expenditure reports to DHS using the DHS template.

**APPENDIX A**  
**OREGON H1N1 PROVIDER AGREEMENT**

**H1N1 Flu Vaccine Registration**

- I. The H1N1 immunization provider agrees to the following:**
- A.** Administer the H1N1 vaccine only according to the recommendations of CDC's Advisory Committee on Immunization Practices.
  - B.** Store and handle the vaccine in accordance with the package insert provided with the vaccine.
  - C.** Refrigerators used for H1N1 vaccine must be stored as follows:
    - 1.** Units must not be used for anything except pharmaceuticals,
    - 2.** Units must be equipped with a commercial grade thermometer.
    - 3.** Units must not be dormitory style refrigerators.
    - 4.** Temperatures must be read and logged at least once daily for each refrigerator unit.
  - D.** Provide a current Vaccine Information Statement (VIS) to each individual vaccinated, and answer questions about the benefits and risk of vaccination, including different indications for live versus inactivated vaccines.
  - E.** Record the date of administration, the anatomical site of administration, the publication date of the current VIS, the date the VIS was given to the patient/guardian, 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.
  - F.** Information on doses administered must be submitted to the ALERT Immunization Registry within 14 days of vaccine administration. Users who currently submit information can use their regular format; other submission options include on-line data entry or using ALERT scannable forms. With the scan technique, providers will keep photocopies of each double-sided completed form and mail originals to the registry in postage-paid envelopes. OIP staff will scan data into the registry. Postage paid envelopes will be provided.

- 1. Oregon Immunization ALERT is a statewide immunization information system. The system contains immunization records of individuals who receive immunizations in Oregon, from either public or private providers. ALERT helps health care providers and other authorized users as defined below to know an individual's immunization status.**
2. State law and Oregon Administrative Rules cover collection and release of information in ALERT. Under ALERT's law, information is confidential and can only be shared with authorized users, including an individual's health care provider, school, childcare facility, insurer, local health department, or parent if person is a minor. Though information is confidential, the law allows providers to share this immunization information with authorized users without consent. Information from ALERT may not be used in any way to penalize an individual or organization.
3. As a condition of receiving immunization information from ALERT as a provider (defined in ORS 433.090), we agree to the following:
  - a. Only access immunization information in ALERT for individuals under our care.
  - b. Read and abide by the ALERT Confidentiality Policy.
  - c. Abide by all security policies and procedures, including safeguarding our user identification number(s) and computer password(s) against unauthorized use.
  - d. Permit the ALERT Director to monitor and audit our use of the system.

**G.** Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (<http://www.vaers.hhs.gov/contact.htm>).

**II. In addition, the provider:**

- A.** May not charge patients, health insurance plans, and other third party payers for the vaccine, syringes or needles as these are provided at no cost to the provider.
- B.** 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. For

individuals enrolled in Medicaid, the administration fee is billed to Medicaid and cannot exceed the state Medicaid administration fee.

- C. Is not obligated to provide H1N1 vaccine to those unable to pay the administration fee, however, individuals who cannot afford the administration fee should be referred to a public health department clinic or affiliated public health provider for vaccination.
- D. 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 destroyed in accordance to state regulations for biological waste.
- E. 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 ancillary supplies.
- F. Agreement to receive communications about H1N1 from OIP via an email listserv.
- G. H1N1 vaccine cannot be shared with any clinic or provider without explicit permission from the local health department, tribal organization or state agency. Any doses transferred between providers must be reported to OIP weekly using state-supplied transfer form.

### **III. Communication:**

The Immunization Program will periodically email or blast fax vaccine information updates to registered sites to help them prepare. This will include information to access required Agreement forms as well as H1N1 vaccine order forms. The agreement will outline the terms and conditions of vaccine use as defined by federal and state authorities.