

## **Program Element #43: Immunization Services**

### **OHA Program Responsible for Program Element:**

Public Health Division/Center for Public Health Practice, Immunization Section

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 deliver Immunization Services.

Immunization Services are provided in the community to prevent and mitigate vaccine-preventable diseases for all people by reaching and maintaining high lifetime immunization rates. Services include population-based services including public education to increase vaccine confidence, enforcement of school immunization requirements, and technical assistance for healthcare providers that provide vaccines to their client populations, as well as vaccine administration to vulnerable populations with an emphasis on ensuring access and equity for all persons in the jurisdiction.

This Program Element, and all changes to this Program Element are effective the first day of the month noted in the Issue Date section of Exhibit C of the Financial Assistance Award unless otherwise noted in Comments and Footnotes of Exhibit C of the Financial Assistance Award.

### 2. **Definitions Specific to Immunization Services.**

- a. **ALERT IIS:** OHA's statewide immunization information system.
- b. **Billable Doses:** Vaccine doses given to individuals who opt to pay out of pocket or are insured for vaccines, including adults on Medicare and/or the Oregon Health Plan
- c. **Case Management:** An individualized plan for securing, coordinating, and monitoring disease-appropriate treatment interventions.
- d. **Centers for Disease Control and Prevention or CDC:** Federal Centers for Disease Control and Prevention.
- e. **Clinical Immunization Staff:** LPHA staff that administer immunizations or who have authority to order immunizations for patients.
- f. **Delegate Addendum:** A document serving as a contract between LPHAs and an outside agency agreeing to provide Immunization Services under the umbrella of the LPHA. The Addendum is signed in addition to a Public Provider Agreement and Profile.
- g. **Delegate Agency:** An immunization clinic that is subcontracted with the LPHA for the purpose of providing Immunization Services to targeted populations.
- h. **Deputization:** The process that allows Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) to authorize local health departments (LHDs) to vaccinate underinsured VFC-eligible children.
- i. **Electronic Health Record (EHR) or Electronic Medical Record (EMR):** A digital version of a patient's paper medical chart.
- j. **Emergency Use Authorization or EUA:** Federally required patient handouts produced by the FDA with information about the risks and benefits of vaccines authorized for emergency use.
- k. **Exclusion Orders:** Legal notification to a parent or guardian of their child's noncompliance with the School/Facility Immunization Law.
- l. **Forecasting:** Determining vaccines due for an individual, based on immunization history and age.
- m. **HBsAg Screening:** Testing to determine presence of Hepatitis B surface antigen, indicating the individual carries the disease.

- n. **Immunization Quality Improvement for Providers (IQIP):** A continuous quality improvement process developed by CDC to improve clinic immunization rates and practices. Previously called AFIX.
  - o. **Oregon Vaccine Stewardship Statute:** State law requiring all Vaccine Access Program enrolled providers to:
    - (1) Submit all vaccine administration data, including dose level eligibility codes, to ALERT IIS;
    - (2) Use ALERT IIS ordering and inventory modules; and
    - (3) Verify that at least two employees have current training and certification in vaccine storage, handling and administration, unless exempt under statute.
  - p. **Orpheus:** An electronic communicable disease database and surveillance system intended for local and state public health epidemiologists and disease investigators to manage communicable disease reporting.
  - q. **Public Provider Agreement and Profile:** Signed agreement between OHA and LPHA that receives vaccines through VAP or VFC. Agreement includes clinic demographic details, program requirements and the number of patients vaccinated.
  - r. **Service Area:** Geographic areas in Oregon served by immunization providers.
  - s. **Surveillance:** The routine collection, analysis and dissemination of data that describe the occurrence and distribution of disease, events or conditions.
  - t. **Vaccine Access Program (VAP):** Vaccine or Immune Globulin procured by the OHA with state and federal funds used to assure vaccine availability to specified groups.
  - u. **Vaccine Adverse Events Reporting System (VAERS):** Federal system for reporting adverse events following vaccine administration.
  - v. **Vaccine Eligibility:** An individual's eligibility for VAP based on insurance coverage for immunization.
  - w. **Vaccines for Children (VFC) Program:** A Federal entitlement program providing no-cost vaccines to children 0 through 18 years who are:
    - (1) American Indian/Alaskan Native; or,
    - (2) Uninsured; or,
    - (3) Medicaid-enrolled; or,
    - (4) Underinsured and are served in Federally Qualified Health Centers (FQHC) or Rural Health Centers (RHC); or,
    - (5) Underinsured and served by LPHAs that have Deputization agreements with FQHCs/RHCs.
  - x. **Vaccines for Children Site Visit:** An on-site visit conducted at least every two years to ensure compliance with state and federal VFC requirements.
  - y. **Vaccine Information Statement (VIS):** Federally required patient handouts produced by the CDC with information about the risks and benefits of each vaccine.
3. **Alignment with Modernization Foundational Programs and Foundational Capabilities.** The activities and services that the LPHA has agreed to deliver under this Program Element align with Foundational Programs and Foundational Capabilities and the public health accountability metrics (if applicable), as follows (see [Oregon's Public Health Modernization Manual](#),

([http://www.oregon.gov/oha/PH/ABOUT/TASKFORCE/Documents/public\\_health\\_modernization\\_manual.pdf](http://www.oregon.gov/oha/PH/ABOUT/TASKFORCE/Documents/public_health_modernization_manual.pdf)):

**a. Foundational Programs and Capabilities** (As specified in Public Health Modernization Manual)

Program Components	Foundational Program					Foundational Capabilities							
	CD Control	Prevention and health promotion	Environmental health	Population Health	Access to clinical preventive services Direct services	Leadership and organizational competencies	Health equity and cultural responsiveness	Community Partnership Development	Assessment and Epidemiology	Policy & Planning	Communications	Emergency Preparedness and Response	
<i>Asterisk (*) = Primary foundational program that aligns with each component</i>					<i>X = Foundational capabilities that align with each component</i>								
<i>X = Other applicable foundational programs</i>													
<b>Vaccines for Children Program Enrollment</b>					*		X					X	
<b>Oregon Vaccine Stewardship Statute</b>					*	X							
<b>Vaccine Management</b>					*							X	
<b>Billable Doses/IG</b>					*		X						
<b>Delegate Agencies</b>					*			X					
<b>Vaccine Administration</b>					*							X	
<b>Immunization Rates, Outreach and Education</b>				*									
<b>Tracking and Recall</b>				*					X				
<b>Surveillance of Vaccine-Preventable Diseases</b>	*								X				
<b>Adverse Events Following Immunizations</b>					*								
<b>Perinatal Hepatitis B Prevention, Screening and Documentation</b>	*								X				
<b>School/Facility Immunization Law</b>				*					X				

**b. The work in this Program Element helps Oregon’s governmental public health system achieve the following Public Health Accountability Metric:**

Two-year-old vaccination rates.

**c. The work in this Program Element helps Oregon’s governmental public health system achieve the following Public Health Modernization Process Measure:**

IQIP program.

4. **Procedural and Operational Requirements.** By accepting and using the Financial Assistance awarded under this Agreement and for this Program Element, LPHA agrees to conduct activities in accordance with the following requirements:
- a. **Vaccine Access Program OR Vaccines for Children Program Enrollment.** LPHA must maintain enrollment as an active VAP provider or VFC Provider. In addition, if LPHA contracts out for clinical services, LPHA must ensure that Subcontractor maintains enrollment as an active VAP or VFC Provider.
  - b. **Oregon Vaccine Stewardship Statute.** LPHA must comply with all sections of the Oregon Vaccine Stewardship Statute.
  - c. **Vaccine Management.**
    - (1) LPHA must conduct a monthly, physical inventory of all vaccine storage units and must reconcile their inventory in ALERT IIS. Inventories must be kept for a minimum of three years.
    - (2) LPHA must submit vaccine orders according to the tier assigned by the OHA's Immunization Program.
  - d. **Billable Doses/Immune Globulin .**
    - (1) OHA will bill LPHA quarterly for Billable Doses of vaccine.
    - (2) OHA will bill the published price in effect at the time the vaccine dose is administered.
    - (3) LPHA may not charge or bill a patient more for the vaccine than the published price.
    - (4) Payment is due 30 days after the invoice date.
  - e. **Delegate Agencies.**

If LPHA has a Subcontract for Immunization Services, LPHA must complete a Delegate Addendum. A new Delegate Addendum must be signed when either of the authorized signers changes or upon request.
  - f. **Vaccine Administration.**
    - (1) Vaccines must be administered as directed in the most current, signed version of OHA's Model Standing Orders for Immunizations.
    - (2) LPHA must ensure that Clinical Immunization Staff annually view a minimum of one hour of immunization-specific continuing education like the Epidemiology and Prevention of Vaccine-Preventable Diseases program **or** the annual Immunization Update. Other immunization continuing education from sources like the CDC, Children's Hospital of Philadelphia, American Academy of Pediatrics, etc. are also acceptable.
    - (3) In connection with the administration of a vaccine, LPHA must:
      - (a) Confirm that a recipient, parent, or legal representative has read, or has had read to them, the EUA or VIS and has had their questions answered prior to the administration of the vaccine.
      - (b) Make the EUA or VIS available in other languages or formats when needed (e.g., when English is not a patient's primary language or for those needing the EUA VIS in braille).
      - (c) Provide to the recipient, parent or legal representative, documentation of vaccines received at visit. LPHA may provide a new immunization record or update the recipient's existing handheld record.

- (d) Screen for contraindications and precautions prior to administering vaccine and document that screening has occurred.
- (e) Document administration of an immunization using a vaccine administration record or electronic equivalent, including all federally-required charting elements, in a permanent medical record. (Note- ALERT IIS does not record all federally-required elements and cannot be used as a replacement for this requirement.)
- (f) If LPHA documents vaccine administration electronically, LPHA must demonstrate the ability to override a VIS date in their EHR system.
- (g) Comply with state and federal statutory and regulatory retention schedules, available for review at <http://arcweb.sos.state.or.us/doc/recmgmt/sched/special/state/sched/20120011oha-phdrrs.pdf>, or OHA's office located at 800 NE Oregon St, Suite 370, Portland, OR 97232.
- (h) Comply with Vaccine Billing Standards as provided in Attachment 1 to this PE, incorporated by reference.

**g. Immunization Rates, Outreach and Education.**

- (1) OHA will provide annually to LPHA their IQIP rates and other population-based county rates.
- (2) LPHA must, during the state fiscal year, design and implement two educational or outreach activities in their Service Area (either singly or in collaboration with other community and service provider organizations) designed to raise immunization rates. Activities may include:
  - Activities intended to reduce barriers to immunization, or special immunization clinics that provide vaccine for flu prevention or school children.
  - One of these activities must be related to promoting IQIP participation with local VFC-enrolled clinics. This activity may also be outreach to a local coordinated-care organization to promote IQIP activities.

**h. Tracking and Recall.**

- (1) LPHA must provide Forecasting for clients requiring Immunization Services using the ALERT IIS electronic Forecasting system.
- (2) LPHA must review their patients on the statewide recall list(s) in the first two weeks of the month and make any necessary demographic or immunization updates.
- (3) LPHA must cooperate with OHA to recall a client if a dose administered by LPHA to such client is found by LPHA or OHA to have been mishandled and/or administered incorrectly, thus rendering such dose invalid.

**i. Surveillance of Vaccine-Preventable Diseases.** LPHA must conduct Surveillance within its Service Area in accordance with the Communicable Disease Administrative Rules, the Investigation Guidelines for Notifiable Diseases, the Public Health Laboratory User's Manual, and the Model Standing Orders for Vaccine, available for review at:

<http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease>  
<http://public.health.oregon.gov/LaboratoryServiceshttp://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Pages/provresources.aspx>

**j. Adverse Events Following Immunizations.**

LPHA must complete and electronically file a VAERS form if:

- (1) An adverse event following immunization administration occurs, as listed in "Reportable Events Following Immunization", available for review at <http://vaers.hhs.gov/professionals/index#Guidance1>;
- (2) An event occurs that the package insert lists as a contraindication to additional vaccine doses;
- (3) OHA requests a 60-day and/or one year follow-up report to an earlier reported adverse event; or
- (4) Any other event LPHA believes to be related directly or indirectly to the receipt of any vaccine administered by LPHA or others occurs within 30 days of vaccine administration, and results in either the death of the person or the need for the person to visit a licensed health care provider or hospital.

**k. Perinatal Hepatitis B Prevention, Screening and Documentation**

- (1) LPHA must provide Case Management services to all confirmed or suspect HBsAg-positive mother-infant pairs identified by LPHA or OHA in LPHA's Service Area.
- (2) Case Management will be performed in accordance with the Perinatal Hepatitis B Prevention Program Guidelines posted on the OHA website at <https://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/hepbperi.pdf> and must include, at a minimum:
  - (a) Screen for HBsAg status or refer to a health care provider for screening of HBsAg status, all pregnant women receiving prenatal care from public prenatal programs.
  - (b) Work with birthing hospitals within LPHA's Service Area when maternal screening and documentation of hepatitis B serostatus in the Electronic Birth Registration System drops below 95%.
  - (c) Work with birthing hospitals within LPHA's Service Area when administration of the birth dose of hepatitis B vaccine drops below 80% as reported in the Electronic Birth Registration System.
  - (d) Ensure that laboratories and health care providers promptly report HBsAg-positive pregnant women to LPHA.
  - (e) Provide Case Management services to HBsAg-positive mother-infant pairs to track administration of hepatitis B immune globulin, hepatitis B vaccine doses and post-vaccination serology.
  - (f) Provide HBsAg-positive mothers with initial education and referral of all susceptible contacts for hepatitis B vaccination.

**l. School/Facility Immunization Law**

- (1) LPHA must comply with the Oregon School Immunization Law, Oregon Revised Statutes 433.235 - 433.284, available for review at [https://www.oregonlegislature.gov/bills\\_laws/ors/ors433.html](https://www.oregonlegislature.gov/bills_laws/ors/ors433.html).
- (2) LPHA must take orders for and deliver Certificate of Immunization Status (CIS) forms to schools and children's facilities located in their jurisdiction. Bulk orders of CIS forms will be provided to the LPHA by the state.
- (3) LPHA must cover the cost of mailing/shipping to parents and to schools all Exclusion Orders, school-facility packets which are materials for completing the annual school/facility exclusion process as required by the Oregon School Immunization Law, Oregon Revised Statutes 433.235 - 433.284 and the administrative rules promulgated pursuant thereto,

which can be found at

[https://secure.sos.state.or.us/oard/displayDivisionRules.action%3bJSESSIONID\\_OARD=2rAGjMwAFKyKGiwldp\\_03oUv7xal6kjlhXdVWS78XLgPdYNa0jj7%21479495115?selecte dDivision=1265](https://secure.sos.state.or.us/oard/displayDivisionRules.action%3bJSESSIONID_OARD=2rAGjMwAFKyKGiwldp_03oUv7xal6kjlhXdVWS78XLgPdYNa0jj7%21479495115?selecte dDivision=1265). LPHA may use electronic mail as an alternative or an addition to

mailing/shipping if the LPHA has complete electronic contact information for all schools and children’s facilities, and can confirm receipt of materials.

- (4) LPHA must complete an annual Immunization Status Report that contains the immunization levels for attendees of: certified childcare facilities; preschools; Head Start facilities; and all schools within LPHA’s Service Area. LPHA must submit this report to OHA no later than 23 days after the third Wednesday of February of each year in which LPHA receives funding for Immunization Services under this Agreement.

**m. Supplemental Funding Opportunities**

- (1) LPHA may apply for additional supplemental funding grants by submitting an application outlining activities and timelines. The application is subject to approval by the OHA Immunization Program.
- (2) At the discretion of the OHA Immunization Program, a supplemental funding opportunity may not require application, but will be distributed through a formula approved by the Conference of Local Health Officials.
- (3) LPHA may receive mini-grant funds from the Immunize Oregon Coalition. If LPHA is awarded such funds, it will fulfill all activities required to meet the mini-grant’s objectives, submit reports as prescribed by Immunize Oregon, and utilize the funds in keeping with mini-grant guidance.

**5. General Revenue and Expense Reporting.** LPHA must complete an “Oregon Health Authority Public Health Division Expenditure and Revenue Report” located in Exhibit C of the Agreement. These reports must be submitted to OHA each quarter on the following schedule:

<b>Fiscal Quarter</b>	<b>Due Date</b>
First: July 1 – September 30	October 30
Second: October 1 – December 31	January 30
Third: January 1 – March 31	April 30
Fourth: April 1 – June 30	August 20

**6. Reporting Requirements.**

- a. LPHA must submit vaccine orders according to the ordering tier assigned by OHA.
- b. If LPHA is submitting vaccine administration data electronically to ALERT IIS, LPHA must electronically flag clients who are deceased or have moved out of the Service Area or the LPHA jurisdiction.
- c. LPHA must complete and return a VAERS form to OHA if any of the conditions precedent set forth at Section 4.j. of this Program Element occur.
- d. LPHA must complete and submit an Immunization Status Report as required in Section 4.l.(4) of this Program Element.
- e. LPHA must submit a written corrective action plan to address any compliance issues identified at the triennial review site visit.
- f. LPHA must submit any status reports required by supplemental grants accepted by the LPHA.

**7. Performance Measures.**

- a.** LPHA must operate Immunization Services in a manner designed to achieve the following public health accountability process measure: Percent of Vaccines for Children clinics that participate in the IQIP program.
- b.** If LPHA provides Case Management to 5 births or more to HBsAg-positive mothers annually LPHA must ensure that 90% of babies receive post-vaccination serology by 15 months of age. If LPHA's post-vaccination serology rate is lower than 90%, LPHA must increase the percentage of babies receiving post-vaccination serology by at least one percentage point.
- c.** LPHA must achieve VFC vaccine accounting excellence in all LPHA-operated clinics in the most recent quarter. Clinics achieve vaccine accounting excellence by:
  - (1)** Accounting for 95% of all vaccine inventory in ALERT IIS.
  - (2)** Reporting fewer than 5% of accounted for doses as expired, spoiled or wasted during the quarter.
  - (3)** Recording the receipt of vaccine inventory in ALERT IIS.
- d.** LPHA must receive 95% of Primary Review Summary follow-up reports (Sections E-H) from schools and children's facilities within 21 days of the annual exclusion day. LPHA must follow the steps outlined in OAR 333-050-0095 with any school or facility that does not submit a follow-up report in a timely manner.



## Attachment 1

### OREGON'S IMMUNIZATION BILLING STANDARDS

#### Standards for providing and billing for immunization services in Oregon's Local Public Health Authorities (LPHAs)

**Purpose: To standardize and assist in improving immunization billing practice**

#### Guiding Principles

A modern LPHA understands their actual costs of doing business and dedicates resources to assuring continued financially viable operations. As such:

1. LPHAs should continually assess immunization coverage in their respective communities, assure that vaccine is accessible to all across the lifespan, and bill appropriately for services provided by the LPHA.
2. LPHAs who serve insured individuals should work to develop and continuously improve immunization billing capacity that covers the cost of providing services to those clients (e.g., develop agreements or contracts with health plans, set up procedures to screen clients appropriately, and bill vaccine administration fees that reflect the actual cost of services).
3. Public and private health plans should reimburse LPHAs for the covered services of their members, with vaccine serum and administration fees reimbursed at 100% of actual costs.
4. Each LPHA is uniquely positioned to assess the appropriate implementation of these standards. For example, Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) are obligated to follow a certain set of rules that may differ from these standards.
5. LPHAs that contract out some or all clinical immunization services should consider including these standards in their contracts as expectations of the contracted service provider.

Standards require that an LPHA that provides immunization services:

- Identify staff responsible for billing and contracting activities, dedicating at least a portion of one or more full-time equivalent (FTEs) positions to meet agency billing needs
- Determine vaccine administration fees based on the actual cost of service and document how fees were determined

- Charge the actual costs for vaccine administration fees for all clients and discount the fee(s) as needed by contract, rule, or internal policy approved by OIP
- Develop immunization billing policies and procedures that address:
  - Strategies to manage clients who require vaccines by state law, are not eligible for VFC or 317 and are unable to meet the cost of immunizations provided (out of network or unaffordable cost sharing)
  - The purchasing of privately owned vaccine and how fees are set for vaccine charges to the client
  - The appropriate charge for vaccine purchased from OIP, by including a statement that says, “We will not charge more than the OIP-published price for billable vaccine.”
  - Billing processes based on payor type (Medicaid/CCOs, private insurance, etc.), patient age, and vaccine eligibility
- With certain limited exceptions as published in vaccine eligibility charts, use no federally funded vaccine on insured clients, including adult Medicaid and all Medicare clients
- Identify and develop contracts or other appropriate agreements with relevant payors – including Coordinated Care Organizations (CCOs) to assure access to immunization services for insured members of the community
- Bill private and public health plans directly for immunization services, when feasible, rather than collecting fees from the client and having them submit for reimbursement
- Conduct regular quality assurance measures to ensure costs related to LPHA’s immunization services are being covered
- Work to assure access to immunizations for Medicare-eligible members of the community and, if access is poor, provide Medicare Part B and/or Part D vaccines, as needed, and bill appropriately to cover the cost