

Program Element #43: Immunization Services

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- 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, 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 in service delivery.

All changes to this Program Element are effective upon receipt of grant award unless otherwise noted in Exhibit C of the Financial Assistance Award. Use of any fees collected for purpose of Immunization Services will be dedicated to and only used for payment of such services.

2. Definitions Specific to Immunization Services.

- a. ALERT IIS:** OHA's statewide immunization information system.
- b. Assessment, Feedback, Incentives, & eXchange or AFIX:** A continuous quality improvement process developed by CDC to improve clinic immunization rates and practices.
- c. Billable Doses:** Vaccine doses given to individuals who opt to pay out of pocket or are insured for vaccines.
- d. Case-management:** An individualized plan for securing, coordinating, and monitoring disease-appropriate treatment interventions.
- e. Centers for Disease Control and Prevention or CDC:** Federal Centers for Disease Control and Prevention.
- f. Clinical Immunization Staff:** LPHA staff that administer immunizations or who have authority to order immunizations for patients.
- g. Delegate Addendum:** A document serving as a contract between a LPHAs and an outside agency agreeing to provide Immunization Services under the umbrella of the LPHA. The Addendum is signed in addition to a VFC Public Provider Agreement and Profile.
- h. Delegate Agency:** An immunization clinic that is subcontracted with the LPHA for the purpose of providing Immunization Services to targeted populations.
- i. 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.
- j. Electronic Health Record (EHR) or Electronic Medical Record (EMR):** a digital version of a patient's paper medical chart.
- 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. Oregon Vaccine Stewardship Statute:** State law requiring all VFC-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.
 - o. 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.
 - p. Public Provider Agreement and Profile:** Signed agreement a between OHA and LPHA that receives State-Supplied Vaccine/IG. Agreement includes clinic demographic details, program requirements and the number of patients vaccinated.
 - q. Section 317:** Funding that provides no cost vaccine to individuals who meet eligibility requirements based on insurance status, age, risk factors, and disease exposure.
 - r. Service Areas:** Geographic areas in Oregon served by immunization providers.
 - s. State-Supplied Vaccine/IG:** Vaccine or Immune Globulin provided by the OHA procured with federal and state funds.
 - t. Surveillance:** The routine collection, analysis and dissemination of data that describe the occurrence and distribution of disease, events or conditions.
 - u. Vaccine Adverse Events Reporting System or VAERS:** Federal system for reporting adverse events following vaccine administration.
 - v. Vaccine Eligibility:** An individual's eligibility for state-supplied vaccine 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 or VIS:** Federally-required patient handouts produced by CDC with information about the risks and benefits of each vaccine.
- 3. Program Components.** Activities and services delivered under this Program Element align with Foundational Programs and Foundational Capabilities, as defined in [Oregon's Public Health Modernization Manual](http://www.oregon.gov/oha/PH/ABOUT/TASKFORCE/Documents/public_health_mode), (http://www.oregon.gov/oha/PH/ABOUT/TASKFORCE/Documents/public_health_mode)

[rnization_manual.pdf](#)) as well as with public health accountability outcome and process metrics (if applicable) as follows:

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	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>												
Vaccines for Children Program Enrollment				X	*		X					X
Oregon Vaccine Stewardship Statute					*	X						
Vaccine Management				X	*							X
Billable Vaccine/IG				X	*		X					
Delegate Agencies				X	*X			X				
Vaccine Administration				X	*							X
Immunization Rates, Outreach and Education				*X								
Tracking and Recall				*					X			
Surveillance of Vaccine-Preventable Diseases	*								X			
Adverse Events Following Immunizations					*							
Perinatal Hepatitis B Prevention, Screening and Documentation	*								X			
School/Facility Immunization Law	X			*					X			

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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: Percent of Vaccines for Children clinics that participate in the Assessment, Feedback, Incentives and eXchange (AFIX) program.

~~b. Public Health Accountability Outcome Metric: (Enter PH Accountability Outcome Metric(s) related to this PE, or "Not applicable")~~

~~e. Public Health Accountability Process Measure: (Enter the PH Accountability Process Measure or "Not applicable")~~

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:

- ~~4.~~ **Vaccines for Children State-Supplied Vaccine Provider OR Vaccines for Children Program Enrollment.** LPHA must maintain enrollment as an active state-supplied vaccine provider or VFC Provider. In addition, if LPHA contracts out for clinical services, LPHA must ensure that contractor maintains enrollment as an active VFC Provider.
- a. **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 will reconcile their inventory in ALERT IIS. Inventories will 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 Vaccine/IG.**
- (1) LPHA will be billed quarterly by the OHA 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.**
- (1) LPHA's that have an agreement with other agencies for Immunization Services will complete a Delegate Addendum. A new Delegate Addendum must be signed when either of the authorized signers changes or upon request.
 - (2) (Quality Assurance only) LPHA must participate in Delegate Agency's biennial VFC compliance site visits with an OHA site visit reviewer.
- f. **Vaccine Administration.**

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- (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. Both are available as a DVD or a web-on-demand from the CDC's website.
- (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 VIS and has had their questions answered prior to the administration of the vaccine.
 - (b) Make the 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 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. (Note- ALERT IIS does not record all federally-required elements and cannot be used as a replacement for this requirement.)
 - (f) LPHAs documenting vaccine administration electronically must demonstrate the ability to override a VIS date in their EHR system.
 - (g) LPHA must 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/20120011ohaphdrrs.pdf>, or OHA's office located at 800 NE Oregon St, Suite 370, Portland, OR 97232.
 - (h) LPHA must comply with Vaccine Billing Standards. See Appendix A to this Program Element.

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

- (1) OHA will provide annually to LPHA their AFIX rates and other population-based county rates. 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.

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~~(2) These educational and outreach activities~~ may include activities intended to reduce barriers to immunization, or special immunization clinics that provide vaccine for flu prevention or school children.

~~(3) One of these activities must be related to promoting AFIX participation with local VFC-enrolled clinics. This activity may also be outreach to a local coordinated-care organization to promote AFIX activities.~~

h. Tracking and Recall.

- (1) LPHA must forecast immunizations due 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 disease 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/LaboratoryServices>
<http://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.

~~(5) LPHA must email a copy of the VAERS report number to OHA as soon as possible after filing the VAERS report.~~

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/epbperi.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.

I. 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 <http://1.usa.gov/OregonSchool>.
- (2) LPHA must take orders for and deliver Certificate of Immunization Status 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 all Exclusion Orders to parents and to schools, 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 <http://1.usa.gov/OregonImmunizationLaw>. 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 will 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. Affordable Care Act Grants/Prevention and Public Health Project Grants

- (1) If one time only funding becomes available, Oregon LPHAs may opt in by submitting an application outlining activities and timelines. The application is subject to approval by the OHA Immunization Program.
- (2) LPHA may on occasion 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.

- n. State Sponsored Conferences:** LPHA must participate in State-sponsored immunization conference(s) and other training(s). LPHA will receive dedicated funds for one person from LPHA to attend required conference(s) and training(s). If one staff person's travel expenses exceed the dedicated award (based on State of Oregon per diem rates), the State will amend the LPHA's annual award to cover the additional costs. LPHA may use any balance on the dedicated award (after all State-required trainings are attended) to attend immunization-related conference(s) and training(s) of their choice, or further support activities included in this Program Element.

- 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, by the 25th of the month following the end of the fiscal year quarter.

6. Reporting Requirements.

- a.** Vaccine orders must be submitted according to the ordering tier assigned by OHA.
- b.** If LPHA is submitting vaccine administration data electronically to ALERT, LPHA will electronically flag clients who are deceased or have moved out of the Oregon 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 4.1. of this Program Element occur.
- d.** LPHA must complete and submit an Immunization Status Report as required in Section 4.n. 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.

7. Performance Measures.

a. LPHA shall 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 Assessment, Feedback, Incentives and eXchange (AFIX) program.

a.b. LPHAs that case manage 5 births or more to HBsAg-positive mothers annually will ensure that 90% of babies receive post-vaccination serology by 15 months of age. LPHAs whose post-vaccination serology rate is lower than 90% will increase the percentage of babies receiving post-vaccination serology by at least one percentage point.

b.c. LPHA achieves 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.

e.d. 95% of Primary Review Summary follow-up reports (Sections E-H) are received from schools and children's facilities within 21 days of the annual exclusion day. LPHA will 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.

Appendix A

Billing Health Plans in Public Clinics Standards

Purpose: To standardize and assist in improving immunization billing practice

For the purpose of this document, Local Health Department (LHD) will be used to identify the vaccine provider.

Guiding Principles / Assumptions:

1. LHDs should be assessing immunization coverage in their respective communities, assuring that vaccine is accessible to all across the lifespan, and billing appropriately for vaccine provided by the LHD.
2. Health plans should reimburse LHDs for the covered services of their members, with vaccine costs reimbursed at 100%.
3. LHDs who serve insured individuals should work to develop immunization billing capacity that covers the cost of providing services to those clients (e.g., develop agreements or contracts with health plans, when appropriate, set up procedures to screen clients appropriately, and bill an administration fee that reflects the true cost of services.)
4. Oregon Immunization Program (OIP) staff and contractors will work with LHDs and health plans to improve contracting/agreement opportunities and billing processes.
5. Each LHD is uniquely positioned to determine the best methods of meeting both the immunization needs of its community and how to recover the costs of providing services.
6. OIP will work with appropriate CLHO committees to add the standards to Program Element 43 and negotiate the Tier One implementation date.
7. The billing standards are designed as tiers, with Tier One activities laying the foundation for more advanced billing capacity in Tiers Two and Three.

Tier One

The LHD:

- Identifies staff responsible for billing and contracting activities
- Identifies major health insurance plans in the jurisdiction, including those most frequently carried by LHD clients
- Determines an administration fee for Billable clients based on the full cost recovery of services provided and documents how fees were determined
- Charges the maximum allowable vaccine administration fee¹ for all eligible VFC/317 clients and discounts the fee for eligible clients as needed
- Develops immunization billing policies and procedures that address:
 - Strategies to manage clients who are not eligible for VFC or 317 and are unable to meet the cost of immunizations provided
 - The actual cost of administration fees and the adjustments made, if any, to administration fees based on payer, patient age, and/or vaccine eligibility code
 - 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 payer type (DMAP/CCOs, private insurance, etc.), patient age, and vaccine eligibility code
 - The appropriate billing procedures for Medicaid-covered adults²
 - The appropriate billing procedures for Medicaid-covered children birth through 18 years³
 - Is updated annually or as changes occur
- With certain limited exceptions as published in vaccine eligibility charts, uses no federally funded vaccine on insured clients, including adult Medicaid and all Medicare clients⁴
- Implementation will be completed by December 31, 2014.

Tier Two

In addition to all Tier 1 activities, the LHD:

- As needed, considers developing contracts or other appropriate agreements with relevant payers to assure access to immunization services for insured members of the community
- Fulfills credentialing requirements of contracts/agreements
- Bills private and public health plans directly for immunization services, when feasible, rather than collecting fees from the client and having them submit for reimbursement
- Screens immunization clients to determine amount owed for service at all LHD clinics, including those held offsite
- Devises a plan to implement results of administration fee cost analysis

¹ This fee is determined by the Centers for Medicaid and Medicare Services (CMS) for each state

² Uses vaccine eligibility code B for Billable (or L if Locally-owned) and bills DMAP/CCOs for the vaccine and an administration fee that reflects the actual cost of providing immunizations

³ Uses vaccine eligibility code M for OHP/Medicaid clients and bills DMAP/CCOs an administration fee that does not exceed the CMS allowed amount for the State of Oregon, \$21.96 per injection

⁴ Insured clients should be assigned a vaccine eligibility code of B or L

Tier Three

In addition to all Tier 1 and Tier 2 activities, the LHD:

- Conducts regular quality assurance measures to ensure costs related to LHD's immunization services are being covered
- Implements administration charges based on results of the administration fee cost analysis
- Works to assure access to immunizations for Medicare-eligible members of the community and, if access is poor, provides Medicare Part B and/or Part D vaccines, as needed, and bills appropriately to cover the cost

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