

Program Element #43: Family Health Services (“FHS”) – Immunization Services

Funds awarded under this Agreement for Family Health Services must only be used in accordance with and subject to the restrictions and limitations set forth to provide immunization services (“Immunization Services”) as described in detail below.

1. **General Procedural and Operational Requirements, Fees.** Use of any fees collected for purpose of Immunization Services shall be dedicated to such Services.
2. **General Description.** 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. The services include direct services such as education about and administration of vaccines to vulnerable populations, as well as population-based services including public education, enforcement of school immunization requirements, and technical assistance for healthcare providers who are providing vaccines to their client populations.
3. **Definitions Specific to Immunization Services.**
 - a. **Assessment, Feedback, Incentives, & eXchange or AFIX:** A continuous quality improvement process developed by CDC to improve clinic immunization rates and practices. Information about AFIX can be found at <http://www.oregon.gov/dhs/ph/imm/afix/index.shtml>
 - b. **Billable Doses:** Vaccine doses given to individuals who are insured for vaccines and can afford their insurer’s co-pay or deductible.
 - c. **Centers for Disease Control and Prevention or CDC:** Federal Centers for Disease Control and Prevention.
 - d. **Delegate Agency:** Immunization Provider providing Immunization Services pursuant to a subcontract of the LPHA for the purposes of providing immunization services to targeted populations.
 - e. **Exclusion Orders:** Orders notifying a parent or guardian of non-compliance with the School/Facility Immunization Law, available for review at <http://www.oregon.gov/dhs/ph/imm/>
 - f. **FamilyNet:** An integrated, multi-program client data system supplied and maintained by the Department and used by the LPHAs. FamilyNet tracks client service data, including Immunization Services data, as well as data for other services provided by the LPHA.
 - g. **Forecasting:** Determining vaccine doses that are due for an individual, based on the individual’s immunization history and age.
 - h. **IRIS/FamilyNet:** The Immunization Services module for the FamilyNet data system.
 - i. **Monthly Vaccine Report or MVR:** Monthly vaccine inventory report for vaccine accountability filled out by LPHA and submitted to Department covering LPHA and all Delegate Agencies.

- j. **Oregon Immunization ALERT or ALERT:** Department's state-wide immunization registry.
 - k. **Public Provider Agreement:** Signed agreement, required by CDC, between Department and any LPHA that receives State-Supplied Vaccine/IG. LPHA shall comply with the terms and conditions of the Public Provider Agreement, including submitting an annual Public Provider Profile that enumerates the population seen by the LPHA. The Department will maintain and have available for review the signed Public Provider Agreement and Public Provider Profile for Immunization Services at the Department's office located at 800 NE Oregon St, Ste 370, Portland, OR 97232
 - l. **Recall Postcards:** Postcards sent to individuals who are due for an immunization.
 - m. **Self-automated LPHA:** An LPHA that is using its own immunization data system and not using IRIS/FamilyNet.
 - n. **Service Areas:** Geographic areas in Oregon served by Oregon immunization providers.
 - o. **State-Supplied Vaccine/IG:** Vaccine or Immune Globulin provided by the Department including, but not limited to, vaccine procured with federal and state funds. Federal funds support vaccines for the Vaccine for Children Program, an entitlement program that provides free vaccine to children 0 through 18 years who are American Indian/Alaskan Native, uninsured, or on Medicaid; and the 317 Program, a program that provides free vaccine to children and adults who meet eligibility requirements based on insurance status, age, school immunization requirements, risk factors, and disease exposure.
 - p. **Surveillance:** The investigation, confirmation and reporting of communicable diseases and conditions.
 - q. **Tiered Ordering Frequency (TOF):** A CDC process for ordering vaccines, where ordering frequency is linked to provider size, vaccine usage, and storage capacity. LPHA TOF available at: <http://www.immalert.org>.
 - r. **Vaccine Administration Record or VAR:** A Department approved record documenting immunization screening questions asked of an individual receiving a vaccine and the data of the vaccines administered to the individual.
 - s. **Vaccine Adverse Events Reporting System or VAERS:** Federal system for reporting adverse events to administered immunizations, available at <http://vaers.hhs.gov/>
 - t. **Vaccine Eligibility:** An individual's eligibility for state-supplied vaccine. Information about vaccine eligibility is available at the Department website: <http://www.oregon.gov/dhs/ph/imm/>
 - u. **Vaccine Information Statement or VIS:** Information statement about each vaccine that is produced by CDC.
4. **Procedural and Operational Requirements.** All Immunization Services supported in whole or in part with funds provided under this Agreement or delivered with State-Supplied

Vaccine/IG must be delivered in accordance with the following procedural and operational requirements:

a. State-Supplied Vaccine/IG.

- i. LPHA shall appropriately document in the Department developed or approved VAR and report to the Department the appropriate eligibility of the client for State-Supplied Vaccine/IG, using the list of codes and the Vaccine Eligibility charts provided by the Department, Immunization Program, to the LPHA and posted on the website: <http://www.oregon.gov/dhs/ph/imm/>
- ii. LPHA will be billed quarterly by the Department for Billable Doses provided to those clients who are insured for vaccines and can afford their insurer's co-pay or deductible.

b. Vaccine Management & Accountability.

LPHA shall track, store, and manage the supply and distribution of vaccine, according to Department and CDC guidelines set forth in the Public Provider Agreement and the Department's Standard Operating Procedures (SOP) posted on the website: <http://www.oregon.gov/dhs/ph/imm/> Procedures include but are not limited to the following:

- i. LPHA will designate one staff member as primary vaccine coordinator and at least one back-up vaccine coordinator to be responsible for all key vaccine management and accountability requirements per the Public Provider Agreement and SOP.
- ii. Department-approved SOPs for routine and emergency vaccine routines shall be reviewed and updated annually by LPHA, or when there is a change in staff who have responsibilities specified in the plans.
- iii. Routine and Emergency SOPs must include storage and handling plans that include guidance regarding: ordering vaccines; controlling inventory; storing vaccines & monitoring conditions (i.e., twice-daily temperature logging); minimization of vaccine wastage; proper vaccine stock rotation; vaccine receiving, packing and transporting; emergency contact information & event plans; and documentation of all routine and emergency events.
- iv. LPHA will have appropriate refrigeration units and temperature tracking equipment to store vaccine and maintain proper conditions. Certified 24-hour temperature tracking devices that meet NIST or ASTM standards are required to track temperatures in any refrigerator or freezer used to store vaccine. Whenever a refrigerator or freezer is found to be outside the acceptable temperature range, LPHA must call their State Immunization Health Educator at: (971) 673-0300, for resolution.
- v. LPHA will follow all CDC and Department cold chain requirements. This includes (but is not limited to): following all vaccine off-site transporting protocols and procedures; reporting and responding to vaccine expiration, wastage and compromised cold-chain events; returning all spoiled or expired state-supplied vaccines; prohibition of pre-

drawing vaccines into syringes; and safeguarding of vaccines by providing facility security.

c. Delegate Agencies. All Delegate Agencies to which the LPHA supplies State-Supplied Vaccine/IG must agree to the requirements as spelled out in the County Delegate Agency Vaccine Certification “D”, a copy of which is available from the Department’s Immunization Program at (971) 673-0300.

- i. LPHA shall complete a County Delegate Agency Vaccine Certification “D” for every Delegate Agency biennially. This Certification “D”, when executed by the LPHA and acknowledged and agreed to by a Delegate Agency, serves as the agreement between the LPHA and that Delegate Agency.
- ii. LPHA shall review each Delegate Agency on-site biennially using the Delegate Agency Review Tool, which Department will provide to LPHA.

d. Vaccine Administration.

- i. Annually in accordance with a schedule determined by Department in consultation with LPHA or as requested by Department, LPHA shall submit a duly executed Immunization Program Public Provider Agreement and Public Provider Profile, both of which are requirements of CDC for any LPHA that receives State-Supplied Vaccine/IG. LPHA shall comply with the terms and conditions of the Public Provider Agreement.

Department will maintain and have available for review the signed Immunization Program Public Provider Agreement and Public Provider Profile at the Department’s office located at 800 NE Oregon St, Ste 370, Portland, OR 97232.

- ii. All State-Supplied Vaccine/IG must be offered to appropriate clients and may only be administered in accordance with the current recommendations of the Department of Health and Human Services’ Advisory Committee on Immunization Practices (ACIP) and Department’s Communicable Disease Summaries, as summarized in the Department’s Model Standing Orders for Vaccines, and in accordance with the Standards for Child and Adolescent Immunization Practices and the Standards for Adult Immunization Practices. These documents and standards are available for review at: <http://www.oregon.gov/dhs/ph/imm/>
- iii. In connection with the administration of a vaccine, LPHA must:
 - (A.) Provide to the recipient, parent or legal representative, documentation of vaccines received at visit. May provide a new immunization record or update the recipient’s existing handheld record.
 - (B.) Document administration of the immunization in a permanent file, including: vaccine name, date of administration, vaccine eligibility code, manufacturer and lot number, signature and title of the person administering the dose, address of clinic, date printed on the VIS, date the VIS was given, contraindication

questions, and HIPAA/ALERT signature requirement. At a minimum, retain the Department's "Vaccine Administration Record" or a Department approved equivalent as documentation.

- (C.) LPHA shall comply with state and federal statutory and regulatory retention schedules, available for review at the Department's office located at 800 NE Oregon St, Ste 370, Portland, OR 97232. In cases of claim or lawsuit arising out of the administration of vaccine to any individual, vaccine administration records must be retained until final disposition of the claim, including completion of any appeals.
 - (D.) LPHA shall not impose a charge for the cost of State-Supplied Vaccine/IG, except for Billable Doses. Vaccine charges for Billable doses must not exceed DHS published price list.
 - (E.) LPHA shall not impose a charge for the administration of State-Supplied Vaccine/IG, except for Billable doses, in any amount higher than \$15.19 (per shot), the maximum fee established by Medicaid for the State of Oregon.
 - (F.) LPHA shall not deny administration of a State-Supplied Vaccine/IG to a child seeking such vaccine due to the inability of the child's parent/guardian/individual of record to pay an administration fee. VFC and 317 administration fees must be waived if client unable to pay.
- e. **Immunization Rates and Assessments.** Department shall provide annually to LPHA their AFIX rates and their population-based rate for the entire county. LPHA shall participate in annual AFIX quality improvement activities, and use these rate data to direct immunization activities.
- f. **Perinatal Hepatitis B Prevention.**
- i. LPHA must provide case-management services to all confirmed or suspect HBsAg-positive mother-infant pairs identified by LPHA or Department in LPHA's Service Area. Case management, in accordance with the Perinatal Hepatitis B Prevention Program Guidelines posted on the Department website at: <http://www.oregon.gov/dhs/ph/imm/phepb/index.shtml> shall include, at a minimum:
 - (A.) Notification of the appropriate hospital infection control unit of any pending delivery by an HBsAg-positive pregnant woman who has been reported to the LPHA;
 - (B.) Enrollment of newborn into case management program and initial education and referral of HBsAg-positive mother and her susceptible household and sexual contacts for follow-up care including offering vaccination to all susceptibles;
 - (C.) If LPHA's service area is anywhere in Oregon excluding Washington and Clackamas counties, the LPHA is responsible for documentation of the infant's completion or status of the 3-dose hepatitis B vaccine series by 15 months of age and post-serological testing by 18 months of age. LPHA shall submit such documentation, as applicable, to the Department at the time that each dose is

administered to the infant and/or susceptible household or sexual contact and at the time that the testing is conducted.

- (D.) If LPHA's service area is Multnomah County, the award of funds under this Agreement to LPHA for this Program Element will include funds to implement centralized case management work for the tri-county area, to include Clackamas, Multnomah and Washington counties. The funds awarded for centralized case management work will be identified by footnote in the award. LPHA shall use this portion of the award to fund a position responsible for tracking clients and reporting doses administered and testing completed.

- ii. LPHA shall work with hospitals to promote the administration of Hepatitis B birth doses to all infants and Hepatitis B immune globulin (HBIG) and hepatitis B vaccines to infants born to HBsAg-positive women and women whose HBsAg status is unknown.

g. Tracking and Recall.

- i. LPHA shall forecast shots due for a child eligible for Immunization Services using the IRIS/FamilyNet or ALERT electronic forecast system, or a Department-approved forecasting algorithm.
- ii. LPHA must recall children who previously received vaccinations from LPHA, through the use of monthly recall postcards sent to their parents. Children who must be recalled include those less than five years old who have not received, when appropriate: 4 DTaP, 3 IPV, 1 MMR, 3 Hep B, up to 4 Hib, 1 Varicella or with no history of varicella disease, up to 4 PCV7, and 2 Hep A. At least two postcards must be sent for each past-due vaccine. Other additional methods of recall or reminders are encouraged.
- iii. LPHA must cooperate with the Department to recall a client if a dose administered by LPHA to such client is found by LPHA or the Department to have been mishandled and/or administered incorrectly, thus rendering such dose invalid.

- h. WIC/Immunization Integration.** LPHA must assist and support the efforts of the Department to provide WIC Services in compliance with the intent of the USDA Policy Memorandum #2001-7: Immunization Screening and Referral in WIC, available for review at the Department's office located at 800 NE Oregon St, Ste 370, Portland, OR 97232.

- i. Vaccine Information.** In connection with LPHA's administration of each vaccine, LPHA must:

- i. Provide to the vaccine recipient (or the recipient's parent or legal representative if the recipient is a minor) a copy of CDC's current VIS.
- ii. Confirm that, either 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.

- iii. Make the VIS available in another language (for example, Spanish), if there are significant numbers of individuals seeking vaccines for whom English is not their first language.
- j. **Outreach and Education.** LPHA must, during the state fiscal year, design and implement two educational or outreach activities in LPHA's Service Area (either singly or in collaboration with other community and service provider organizations) for parents and/or private vaccine providers designed to raise childhood and/or adult immunization rates. These educational and outreach activities may include activities intended to reduce barriers to immunization, but may not include special immunization clinics that provide vaccine for school children or flu prevention.
- k. **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 Users Manual, and the Model Standing Orders for Vaccine, available for review at:
- <http://www.oregon.gov/DHS/ph/acd/>
 - <http://www.oregon.gov/DHS/ph/phl/>
 - <http://www.oregon.gov/dhs/ph/imm/>
- l. **Adverse Events Following Immunizations.** LPHA must complete and return a VAERS form to the Department if:
- i. An adverse event to immunization administration occurs, as listed in "Reportable Events Following Immunization", available for review at <http://www.vaers.org>
 - ii. The Department requests a 60-day and or one year follow-up report to an earlier reported adverse event; or
 - iii. 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.
- m. **Hepatitis B Screening and Documentation**
- i. LPHA shall screen for HBsAg status, or refer to a health care provider for screening of HBsAg status, all pregnant women receiving prenatal care from the public prenatal programs.
 - ii. LPHA shall work with hospitals within LPHA's Service Area selected by the Department to strengthen hospital-based screening and documentation of every delivering woman's hepatitis B serostatus.
 - iii. LPHA shall, in accordance with a schedule determined by the Department in consultation with LPHA, develop and implement an action plan to work with hospitals identified by Department or LPHA to improve HBsAg screening for pregnant women.

- iv. LPHA shall cause laboratories and health care providers to promptly report HBsAg-positive pregnant women to LPHA.

n. School/Facility Immunization Law

- i. LPHA must comply with the Oregon School Immunization Law, Oregon Revised Statutes 433.235 — 433.284, available for review at <http://www.oregon.gov/dhs/ph/imm/law/index.shtml>
- ii. LPHA shall complete an annual Immunization Status Report that contains the immunization levels for attendees of: certified childcare facilities; preschools; Head Start facilities; and all schools (K and 7th grade) within LPHA's Service Area. LPHA shall submit this report to the Department no later than the second Friday of March of each year in which LPHA receives funding for Immunization Services under this Agreement.

5. Performance Measures. LPHA shall meet the following performance measures:

- a. LPHA shall improve the 4:3:1:3:3:1 immunization series coverage rate by one (1) percentage point each year and/or maintain a rate of $\geq 90\%$ (4 DTaP, 3 IPV, 1 MMR, 3 Hep B, 3 Hib, 1 Varicella).
- b. LPHA shall reduce their Missed Shot rate by one (1) percentage point each year and/or maintain the rate of $\leq 10\%$.
- c. 95% of all state-supplied vaccines shall be coded correctly per age-eligibility guidelines.
- d. 80% of infants in LPHA's Service Area exposed to perinatal hepatitis B shall be immunized with the 3-dose hepatitis B series by 15 months of age.
- e. 80% of all vaccine administration data shall be data entered within 14 days of administration.

6. Terms and Conditions Particular to LPHA Performance of the Immunization Services.

- a. LPHA shall reimburse the Department for the cost of wasted State-Supplied Vaccine/IG due to:
 - i. Inadequate handling; including, but not limited to: theft/vandalism, lack of thermometers, power failure, or faulty equipment used in the storage and shipment of State-Supplied Vaccine/IG and/or Billables from LPHA to Department or Delegate Agency which does not maintain the vaccine according to manufacturer standards.
 - ii. Untimely return (i.e., within 3-months of expiration) of State-Supplied Vaccine/IG, without prior authorization from the Department.

- b. The Department will issue one initial bill and up to two (2) follow-up bills for the cost of wasted State-Supplied Vaccine/IG and/or Billables for any one quarterly billing period. The Department will not fill future vaccine orders following the third bill until payment is received for the delinquent billing period.
 - c. LPHA must return to the Department, at LPHA's expense, all styrofoam vaccine shipping containers received by LPHA from the Department.
 - d. LPHA shall cover the cost of mailing/shipping to parents, all Exclusion Orders; 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://www.oregon.gov/dhs/ph/imm/law/index.shtmllaw/index.cfm>
 - e. LPHA shall participate in State-sponsored immunization conference(s) or training(s). LPHA shall receive dedicated funds for one person from the LPHA to attend required conference(s) or training(s). If one staff person's travel expenses exceed the dedicated award (based on State of Oregon per diem rates), the State shall 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) or training(s) of their choice.
7. **Reporting Obligations and Periodic Reporting Requirements.** In addition to the reporting requirements set forth in section 8 of Exhibit E of this Agreement, LPHA shall submit the following reports to the Department's Immunization Program:
- a. **Monthly Vaccine Report:** This report must be submitted by the 5th working day of every month and must contain separate vaccine inventory and administration data from all Delegate Agencies.
 - b. **Vaccine Orders:** These orders must be submitted by the 5th working day of each month according to the Tiered Ordering Frequency (TOF) assigned by the Department.
 - c. A copy of the completed **Delegate Review Tool** and **Certificate "D"** for each Delegate Agency must be sent to Department by the date determined by Department in consultation with LPHA, but in any event within two calendar months of the date that LPHA receives the request from Department for the completed Delegate Agency Review Tool and Certification "D".
 - d. LPHA shall submit **vaccine administration data** within 14 days of vaccine administration to the ALERT Registry via IRIS/FamilyNet, electronic data transfer, or barcode/hardcopy submission. If LPHA is submitting vaccine administration data electronically to ALERT, LPHA shall electronically flag clients who are deceased or have moved out of the Oregon Service Area.
 - e. LPHA shall complete and return a **VAERS form** to the Department if any of the conditions precedent set forth at Section 4.m. of this Program Element occur.

- f. LPHA shall complete and submit an **Immunization Status Report** as required in Section 4.o. of this Program Element.
- g. **LPHA shall complete and submit an annual progress report for its triennial plan.** The annual progress report shall be due at the beginning of the month corresponding to their assigned month for triennial agency review. Report format and county schedule is available for review at the Department's office located at 800 NE Oregon St, Ste 370, Portland, OR 97232.
- h. **LPHA shall submit a written corrective action plan** for any unsatisfactory responses to high-priority questions stemming from the triennial review site visit.