

Program Element #03: Tuberculosis Services

OHA Program Responsible for Program Element:

Public Health Division/Center for Public Health Practice/HIV, STD and TB 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 Tuberculosis Services.

ORS 433.006 and OAR 333-019-0000 assign responsibility to LPHA for Tuberculosis (“TB”) investigations and implementation of TB control measures within LPHA’s service area. The funds provided for TB Case Management Services (including contact investigation) and B-waiver Follow-Up under the Agreement for this Program Element may only be used as supplemental funds to support LPHA’s TB investigation and control efforts and are not intended to be the sole funding for LPHA’s TB investigation and control program.

Pulmonary tuberculosis is an infectious disease that is airborne. Treatment for TB disease must be provided by Directly Observed Therapy to ensure the patient is cured and prevent drug resistant TB. Screening and treating Contacts stops disease transmission. Tuberculosis prevention and control is a priority in order to protect the population from communicable disease and is included in the State Health Improvement Plan (SHIP).

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 Financial Assistance Award unless otherwise noted in Comments and Footnotes of Exhibit C of the Financial Assistance Award.

2. Definitions Specific to TB Services

- a. **Active TB Disease:** TB disease in an individual whose immune system has failed to control his or her TB infection and who has become ill with Active TB Disease, as determined in accordance with the Centers for Disease Control and Prevention’s (CDC) laboratory or clinical criteria for Active TB Disease and based on a diagnostic evaluation of the individual.
- b. **Appropriate Therapy:** Current TB treatment regimens recommended by the CDC, the American Thoracic Society, the Academy of Pediatrics, and the Infectious Diseases Society of America.
- c. **Associated Cases:** Additional Cases of TB disease discovered while performing a Contact investigation.
- d. **B-waiver Immigrants:** Immigrants or refugees screened for TB prior to entry to the U.S. and found to have TB disease Latent TB Infection, or an abnormal chest x-ray finding suggestive of TB with negative sputum smears and culture results.
- e. **B-waiver Follow-Up:** B-waiver Follow-Up includes initial attempts by the LPHA to locate the B- waiver immigrant. If located, LPHA proceeds to coordinate or provide TB medical evaluation and treatment as needed. Updates on status are submitted regularly by LPHA using Electronic Disease Network (EDN) or the follow-up worksheet.
- f. **Case:** A Case is an individual, whose illness is confirmed to be Active TB Disease or, whose illness meets defining criteria published in OHA’s Tuberculosis Investigative Guidelines. This diagnosis may be based on signs, symptoms, and/or laboratory findings.
- g. **Cohort Review:** A systematic review of the management of patients with TB disease and their Contacts. The “cohort” is a group of TB Cases counted (confirmed as Cases) over 3 months. The Cases are reviewed 6-9 months after being counted to ensure they have completed treatment or are nearing the end. Details of the management and outcomes of TB Cases are reviewed in a group with the information presented by the case manager.

- h. **Contact:** An individual who was significantly exposed to an infectious Case of Active TB Disease.
- i. **Directly Observed Therapy (DOT):** LPHA staff (or other person appropriately designated by the LPHA) observes an individual with TB disease swallowing each dose of TB medication to assure adequate treatment and prevent the development of drug resistant TB. May be completed in person or by video (VDOT, eDOT) or other technology deemed appropriate by OHA.
- j. **Evaluated (in context of Contact investigation):** A Contact received a complete TB symptom review and tests as described in the definition of Medical Evaluation, below, or in the OHA Tuberculosis Investigative Guidelines.
- k. **Interjurisdictional Transfer:** A Suspected Case, TB Case or Contact transferred for follow-up evaluation and care from another jurisdiction either within or outside of Oregon.
- l. **Investigative Guidelines:** OHA guidelines, which are incorporated herein by this reference are available for review at:
<http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/Tuberculosis/Documents/investigativeguide.pdf>.
- m. **Latent TB Infection (LTBI):** TB infection in a person whose immune system is keeping the TB infection under control. LTBI is also referred to as TB in a dormant stage.
- n. **Medical Evaluation:** A complete medical examination of an individual for TB including a medical history, physical examination, TB skin test or interferon gamma release assay, chest x-ray, and any appropriate molecular, bacteriologic, histologic examinations.
- o. **Suspected Case of Active TB Disease:** A Suspected Case of Active TB Disease, is an individual whose illness is thought by a health care provider, to be Active TB Disease or whose illness meets defining criteria published in OHA's Tuberculosis Investigative Guidelines. This suspicion may be based on signs, symptoms, or laboratory findings.
- p. **TB Case Management Services:** Dynamic and systematic management of a Case of Active TB Disease where a person, known as a TB Case manager, is assigned responsibility for the management of an individual TB Case to ensure completion of treatment. TB Case Management Services requires a collaborative approach to providing and coordinating health care services for the individual. The Case manager is responsible for ensuring adequate TB treatment, coordinating care as needed, providing patient education and counseling, performing Contact investigations and following infected Contacts through completion of treatment, identifying barriers to care and implementing strategies to remove those barriers.

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 Public Health Modernization Manual at 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
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	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
Asterisk (*) = Primary foundational program that aligns with each component						X = Foundational capabilities that align with each component						
X = Other applicable foundational programs												
TB Case Management Services	*					X	X		X			
TB Contact Investigation and Evaluation	*						X		X			
Participation in TB Cohort Review	*						X					
Evaluation of B-waiver Immigrants	*						X		X			

- b. The work in this Program Element helps Oregon’s governmental public health system achieve the following Public Health Accountability Metrics, Health Outcome Indicators:

Not applicable

- c. The work in this Program Element helps Oregon’s governmental public health system achieve the following Public Health Accountability Metrics, LPHA Process Measure:

Not applicable

4. Procedural and Operational Requirements.

By accepting fee-for-service (FFS) funds to provide TB Case Management Services or B-waiver Follow-Up, LPHA agrees to conduct activities in accordance with the following requirements:

- a. LPHA must include the following minimum TB services in its TB investigation and control program if that program is supported in whole or in part with funds provided under this Agreement: TB Case Management Services, as defined above and further described below and in OHA’s Investigative Guidelines.
- b. LPHA will receive \$3500 for each new case of Active TB disease counted in Oregon and documented in Orpheus for which the LPHA provides TB Case Management Services. LPHA will receive \$300 for each new B-waiver Follow-Up.
- c. **TB Case Management Services.** LPHA’s TB Case Management Services must include the following minimum components:
 - (1) LPHA must investigate and monitor treatment for each Case and Suspected Case of Active TB Disease identified by or reported to LPHA whose residence is in LPHA’s jurisdiction, to confirm the diagnosis of TB and ensure completion of adequate therapy.

- (2) LPHA must require individuals who reside in LPHA's jurisdiction and who LPHA suspects of having Active TB Disease, to receive appropriate Medical Evaluations and laboratory testing to confirm the diagnosis of TB and response to therapy, through the completion of treatment. LPHA must assist in arranging the laboratory testing and Medical Evaluation, as necessary.
 - (3) LPHA must provide medication for the treatment of TB disease to all individuals who reside in LPHA's jurisdiction and who have TB disease but who do not have the means to purchase TB medications or for whom obtaining or using identified means is a barrier to TB treatment compliance. LPHA must monitor, at least monthly and in person, individuals receiving medication(s) for adherence to treatment guidelines, medication side effects, and clinical response to treatment.
 - (4) DOT (including VDOT or eDOT) is the standard of care for the treatment of TB disease. Cases of TB disease should be treated via DOT. If DOT is not utilized, OHA's TB Program must be consulted.
 - (5) OHA's TB Program must be consulted prior to initiation of any TB treatment regimen which is not recommended by the most current CDC, American Thoracic Society and Infectious Diseases Society of America TB treatment guideline.
 - (6) LPHA may assist the patient in completion of treatment for TB disease by utilizing the below methods. Methods to ensure adherence should be documented.

 - (a) Proposed interventions for assisting the individual to overcome obstacles to treatment adherence (e.g. assistance with transportation).
 - (b) Proposed use of incentives and enablers to encourage the individual's compliance with the treatment plan.
 - (7) With respect to each Case of TB disease within LPHA's jurisdiction that is identified by or reported to LPHA, LPHA must perform a Contact investigation to identify Contacts, Associated Cases and source of infection. The LPHA must evaluate all located Contacts or confirm that all located Contacts were advised of their risk for TB infection and disease.
 - (8) LPHA must offer or advise each located Contact identified with TB infection or disease, or confirm that all located Contacts were offered or advised, to take Appropriate Therapy and must monitor each Contact who starts treatment through the completion of treatment (or discontinuation of treatment).
- d. If LPHA receives in-kind resources under this Agreement in the form of medications for treating TB, LPHA must use those medications to treat individuals for TB. In the event of a non-TB related emergency (i.e. meningococcal contacts), with notification to TB Program, the LPHA may use these medications to address the emergent situation.
 - e. LPHA must present TB Cases through participation in the quarterly Cohort Review. If the LPHA is unable to present the Case at the designated time, other arrangements must be made in collaboration with OHA.
 - f. LPHA must accept B-waiver Immigrants and Interjurisdictional Transfers for Medical Evaluation and follow-up, as appropriate for LPHA capabilities.
 - g. If LPHA contracts with another person to provide the services required under this Program Element, the in-kind resources in the form of medications received by LPHA from OHA must be provided, free of charge, to the contractor for the purposes set out in this Program Element and the contractor must comply with all requirements related to such medications unless OHA informs LPHA in writing that the medications cannot be provided to the contractor. The LPHA

must document the medications provided to a contractor under this Program Element.

- a. OHA, through CDC Tuberculosis Elimination and Laboratory Cooperative Agreement, will provide in-kind services to LPHAs through technical assistance, clinical consultation, and laboratory related to TB disease and latent TB infection
- b. If LPHA self-certifies as a 340B TB clinic site and receives reimbursement for 340B medications from OHA, it is the sole responsibility of LPHA to comply with all [HRSA regulations and requirements for 340B Drug Pricing Program Covered Entities](#).
- c. Any 340B cost savings or program income realized because of funding from this Agreement must be used in a manner consistent with the goals of the grant or program under which it was authorized; i.e., any cost saving resulting from CDC TB funding must be used to increase, enhance, and support TB screening and treatment services.

5. General Revenue and Expense Reporting.

In lieu of the LPHA completing an “Oregon Health Authority Public Health Division Expenditure and Revenue Report” located in Exhibit C of this Agreement, OHA-PHD will send a pre-populated invoice to the LPHA for review and signature on or before the 5th business day of the month following the end of the first, second, third and fourth fiscal year quarters. The LPHA must submit the signed invoice no later than 30 calendar days after receipt of the invoice from OHA-PHD. The invoice will document the number of new Active TB cases and/or B-waiver Follow-Ups for which the LPHA provided services in the previous quarter. Pending approval of the invoice, OHA- PHD will remit FFS funds to LPHA. Funds under this program element will not be paid in advance or on a 1/12th schedule.

6. Program Reporting Requirements.

LPHA must prepare and submit the following reports to OHA:

- a. LPHA must notify OHA’s TB Program of each Case or Suspected Case of Active TB Disease identified by or reported to LPHA no later than 5 business days within receipt of the report (OR – within 5 business days of the initial case report), in accordance with the standards established pursuant to OAR 333-018-0020. In addition, LPHA must, within 5 business days of a status change of a Suspected Case of TB disease previously reported to OHA, notify OHA of the change. A change in status occurs when a Suspected Case is either confirmed to have TB disease or determined not to have TB disease. LPHA must utilize OHA’s ORPHEUS TB case module for this purpose using the case reporting instructions located at https://www.oregon.gov/oha/PH/DISEASES/CONDITIONS/COMMUNICABLEDISEASE/TUBER_CULOSIS/Pages/tools.aspx . After a Case of TB disease has concluded treatment, case completion information must be entered into the ORPHEUS TB case module within 5 business days of conclusion of treatment.
- b. LPHA must submit data regarding Contact investigations via ORPHEUS or other mechanism deemed acceptable by OHA. Contact investigations are not required for strictly extrapulmonary cases.

7. Performance Measures.

If LPHA uses funds provided under this Agreement to support its TB investigation and control program, LPHA must operate its program in a manner designed to achieve the following national TB performance goals:

- a. For patients with newly diagnosed TB disease for whom 12 months or less of treatment is indicated, **92.0% will complete treatment within 12 months.**
- b. For TB patients with positive acid-fast bacillus (AFB) sputum-smear results, **100.0% (of patients) will be interviewed to elicit Contacts.**
- c. For Contacts of sputum AFB smear-positive TB Cases, **90.0% will be evaluated for infection**

and disease.

- d.** For Contacts of sputum AFB smear-positive TB Cases with newly diagnosed LTBI, **92.0% will start treatment.**
- e.** For Contacts of sputum AFB smear-positive TB Cases that have started treatment for newly diagnosed LTBI, **93.0% will complete treatment.**
- f.** For TB Cases in patients ages 12 years or older with a pleural or respiratory site of disease, **98% will have a sputum culture result reported.**