DRAFT

Formatted: Font: 16 pt

Program Element #03 - Tuberculosis Services

1. Description.

ORS 433.006 and Oregon Administrative Rule 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 under this agreement for this Program Element may only be used, in accordance with and subject to the requirements and limitations set forth below, as supplemental funds to support LPHA's TB investigation and control efforts. The funds provided under this agreement for this Program Element are not intended to be the sole funding for LPHA's TB investigation and control program.

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 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.

Commented [BH1]: Per my interpretation, this would require LPHA's to follow 2016 "Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis" without further modification needed to program element.

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 or latent TB infection.

e. Case: A case is an individual who has been diagnosed by a health care provider, as defined in OAR 333-017-0000, as having a reportable disease, infection, or condition**,** as described in OAR 333-018-0015, or whose illness meets defining criteria published in the Department's Investigative Guidelines.

f. 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.

g. Contact: An individual who was significantly exposed to an infectious case of active TB disease.

h. Directly Observed Therapy (DOT): LPHA staff (or other person appropriately designated by the county) observes an individual with TB disease swallowing each dose of TB medication to assure adequate treatment and prevent the development of drug resistant TB.

Formatted: Font: 16 pt

i. **Evaluated (in context of contact investigation):** A contact received a complete TB symptom review and tests as described in the Department's Investigative Guidelines.

j. **Interjurisdictional Transfer**: A suspected TB ~~suspect~~ case, TB case or contact transferred for follow-up evaluation and care from another jurisdiction either within or outside of Oregon.

k. **Investigative Guidelines:** Department guidelines, dated as of August 2010, which are incorporated herein by this reference are available for review at: http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/Tuberculosis/Documents/investigativeguide.pdf.

l. **Latent TB Infection (LTBI):** TB disease in a person whose immune system is keeping the TB infection under control. LTBI is also referred to as TB in a dormant stage.

m. **Medical Evaluation:** A complete medical examination of an individual for tuberculosis including a medical history, physical examination, TB skin test or -interferon gamma release assay~~QuantiFERON TB Gold test~~, chest x-ray, and any appropriate molecular, bacteriologic, ~~/~~histologic examinations.

n. **Suspected Case:** A suspected case is an individual whose illness is thought by a health care provider, as defined in OAR 333-017-0000, to be likely due to a reportable disease, infection, or condition, as described in OAR 333-018-0015, or whose illness meets defining criteria published in the Department's Investigative Guidelines. This suspicion may be based on signs, symptoms, or laboratory findings.

o. **TB Case Management:** Dynamic and systematic management of a case of TB where a person, known as a case manager, is assigned responsibility for the management of an individual TB case to ensure completion of treatment. TB Case Management 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. Procedural and Operational 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: Tuberculosis Case Management Services, as defined above and further described below and in the Department's Investigative Guidelines.

b. **Tuberculosis Case Management Services.** LPHA's TB Case Management Services must include the following minimum components:

(i) 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.

(ii) LPHA must require individuals who reside in LPHA's jurisdiction and who LPHA suspects of having active TB disease, to receive appropriate medical examinations 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 examination, as necessary.

(iii) LPHA must provide medication for the treatment of TB to all individuals who reside in LPHA's jurisdiction and who have TB 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.

~~LPHA must develop a plan to ensure patient adherence with TB treatment guidelines for each individual within LPHA's jurisdiction identified by or reported to LPHA as having active TB disease. This plan should include the use of DOT for the majority of patients. If DOT will not be used, other methods to ensure patient adherence with treatment guidelines must be utilized and documented (e.g. monthly pill counts or other). Evidence of patient adherence (such as DOT records) must be documented in each individual's chart.~~

(iv) DOT is the standard of care for the treatment of TB. ~~Virtually~~ Cases of TB disease should be treated via DOT. If DOT is not utilized, The Department's TB Program must be consulted.

~~(iv)~~(v) The Department'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.

~~If DOT is not utilized, the LPHA may be asked to justify to Department why DOT was not used for that particular individual.~~

~~The clinical indications and socioeconomic factors listed below are strong indicators that DOT is necessary to ensure adequate treatment of the individual and to prevent acquired drug resistant TB. Patients with the following risk factors must be on DOT. If patients with any of the below circumstances will not be on DOT for any reason during their course of treatment, the Department must be contacted and a plan to ensure compliance discussed.~~

~~(A) Clinical indications which may require DOT include:~~

~~(I) HIV and TB co-infection~~

~~(II) Reactivation of TB disease or history of previous TB treatment~~

~~(III) MDR TB~~

~~(IV) Smear positivity~~

~~(V) Cavitary disease~~

Formatted: Font: 16 pt

Formatted: Indent: Left: 1"

Formatted: Outline numbered + Level: 3 + Numbering Style: i, ii, iii, … + Start at: 1 + Alignment: Right + Aligned at: 0.75" + Tab after: 1" + Indent at: 1"

Formatted: Indent: Left: 1"

Formatted: Font: 16 pt

~~(VI) History of drug and alcohol abuse within the last 6 months~~

~~(VII) Evidence of severe malnourishment with BMI <18.5~~

~~(VIII) Patient < 18 years old~~

~~(B) Socioeconomic factors which require DOT include:~~

~~(I) Homelessness~~

~~(II) History of failure to arrive for clinic appointments and/or noncooperation with LPHA interventions and/or history of non-adherence with prescribed medical therapy (TB or other)~~

~~(III) Presence of child/children or immunocompromised individual in the household~~

~~(IV) Resident of a congregate setting such as jail, long term care facility, group home or homeless shelter.~~

~~(V) Patient unable to self-administer medications due to mental, physical, or emotional impairments~~

~~(VI) Patient shows poor understanding of TB diagnosis, or non-acceptance of diagnosis. Consider level of understanding especially carefully for patients with low literacy and/or low levels of English proficiency.~~

~~(C) Patients not on DOT initially must start DOT if any of the following occur:~~

~~(I) Slow sputum culture conversion (culture still positive > 2 months after treatment started)~~
~~(II) Slow clinical improvement or clinical deterioration while on TB therapy~~
~~(III) Adverse reaction to TB medications~~
~~(IV) Significant interruptions in therapy due to nonadherence~~

~~(v)~~**(vi)** LPHA may assist the patient in completion of treatment 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.

~~(vi)~~**(vii)** With respect to each case of TB within LPHA's jurisdiction that is identified by or reported to LPHA, LPHA shall 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.

~~(vii)~~(viii) The 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 shall monitor each contact who starts treatment through the completion of treatment (or discontinuation of treatment).

c. If LPHA receives in-kind resources under this agreement in the form of medications for treating TB, LPHA shall 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.

d. The LPHA will present TB cases through participation in the quarterly cohort review. If the LPHA is unable to present the TB case at the designated time, other arrangements shall be made in collaboration with the Department.

e. The LPHA will accept Class B waivers and interjurisdictional transfers for evaluation and follow-up, as appropriate for LPHA capabilities.

4. **Reporting Obligations and Periodic Reporting Requirements.** LPHA shall prepare and submit the following reports to the Department:

a. LPHA shall notify the Department'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 shall, within 5 business days of a status change of a suspected case of TB disease previously reported to the Department, notify the Department 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. The LPHA shall utilize the Department's "TB Disease Case Report Form" and ORPHEUS for this purpose. After a case of TB disease has concluded treatment, case completion information shall be sent to the Department's TB Program utilizing the "TB Disease Case Report Form" and ORPHEUS within 5 business days of conclusion of treatment.

b. LPHA shall ~~-~~submit data regarding contact investigation via ORPHEUS or other mechanism deemed acceptable. ~~submit the "TB Contact Investigation Form" to the Department's TB Program in accordance with the timelines described in the instructions for the reporting forms designated by the Department for this purpose .~~ Contact investigations are not required for strictly extrapulmonary cases. Consult with local medical support as needed.

~~**b.**~~

5. **Performance Measures.** If LPHA uses funds provided under this agreement to support its TB investigation and control program, LPHA shall operate its program in a manner designed to achieve the following national TB performance goals by 2015:

Formatted: Font: 16 pt

Formatted: Indent: Left: 2"

Formatted: Indent: Left: 0.25", Tab stops: 0.75", List tab + Not at 1"

Formatted: Indent: Left: 0.25", Tab stops: 0.75", List tab + Not at 1"

Formatted: Indent: Left: 0.25", Tab stops: 0.75", List tab + Not at 1"

Formatted: List Paragraph, No bullets or numbering, Hyphenate, Tab stops: Not at 1"

DRAFT

a. For patients with newly diagnosed TB for whom 12 months or less of treatment is indicated, **93.0% 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 elicited for contacts.**

c. For contacts of sputum AFB smear-positive TB cases, **93.0% will be evaluated for infection and disease.**

d. For contacts of sputum AFB smear-positive TB cases with newly diagnosed latent TB infection (LTBI), **88.0% will start treatment.**

e. For contacts of sputum AFB smear-positive TB cases that have started treatment for newly diagnosed LTBI, **79.0% will complete treatment**.

f. For TB cases in patients ages 12 years or older with a pleural or respiratory site of disease, **95% will have a sputum culture result reported.**

Formatted: Font: 16 pt

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold