Ohio Administrative Code

Rule 3701-22-07 Basic hospital functions.

Effective: September 14, 2024

Each hospital, other than a critical access hospital or a rural emergency hospital, is to provide for the following:

(A) A quality assessment and performance improvement program, in accordance with 42 CFR 482.21. In addition, the hospital will participate in quality assessment and performance improvement projects identified by the director in consultation with the representatives of the regulated industry. Such projects may include those:

(1) Required by the United States centers for medicare and medicaid services or the hospital's accrediting organization; or

(2) For a hospital with a maternity unit and newborn care nursery, implementation of one or more maternal safety bundle(s) developed by the alliance for innovation in maternal health.

(B) Medical staff, in accordance with 42 CFR 482.22;

(C) Nursing services, in accordance with 42 CFR 482.23;

(D) Medical records services, in accordance with 42 CFR 482.24;

(E) Pharmaceutical services, in accordance with 42 CFR 482.25;

(F) Radiologic services, in accordance with 42 CFR 482.26;

(G) Laboratory services, in accordance with 42 CFR 482.27;

(H) Food and dietetic services, in accordance with 42 CFR 482.28;

(I) Utilization review, in accordance with 42 CFR 482.30;

(J) Physical environment, in accordance with 42 CFR 482.41;

(K) Infection prevention and control and antibiotic stewardship programs, in accordance with 42 CFR 482.42. In addition, the hospital will:

(1) Maintain a tuberculosis control plan that meets the standards set forth in rule 3701-15-03 of the Administrative Code;

(2) Implement a written surveillance plan outlining the activities for monitoring/tracking infections based on nationally-recognized surveillance criteria such as the CDC's national healthcare safety network (NHSN) criteria to define infections or other nationally recognized system for hospitals and:

(a) Includes a surveillance system that includes a data collection tool; and

(b) Uses surveillance data to implement timely corrective actions when:

(i) A greater than expected number healthcare-associated infections are detected;

(ii) Transmission of targeted multi-drug resistant organisms (e.g., cre, candida auris) are detected;

(3) Establish and implement an effective water management program to identify hazardous conditions, and take steps to manage the risk of occurrence and transmission of waterborne pathogens, including but not limited to legionella, in building water systems in accordance with guidance from the United States centers for disease control and prevention (available at https://www.cdc.gov/control-legionella/php/toolkit/wmp-toolkit.html) and recommendations of the United States centers for disease control and prevention healthcare infection control practices advisory committee, "Environmental Infection Control Guidelines" (2019) or its successors.

(a) Within the first twelve months, two sets of validation testing in the building water system of each building that provides inpatient medical or surgical services, taken no fewer than four months apart and more than eight months apart, is to occur. Each set of water samples will be representative of all

hot potable water loops and water sources based upon the risk assessment and conditions identified in the water management program, including but not limited to cooling towers, therapy spas, decorative fountains or water features where exposure to aerosols may occur in order to evaluate the performance of the water management program in controlling legionella risk or other waterborne pathogens. A hospital that has demonstrated detections of less than one cfu/ml of legionella through at least two prior validation test sets collected over a one year period may conduct annual validation testing in lieu of twice-yearly testing. Validation testing includes all of the following:

(i) At least one cold water sample obtained from the incoming water mains from the public water system or the water source;

(ii) At minimum, representative samples obtained from distal and proximal locations on each hot water loop on the hot water distribution system; and

(iii) Measurement of total or free chlorine residual, as appropriate, at the time of sample collection, and the observed sustained maximum temperatures for cold and hot water samples.

(b) Collection of water samples under this paragraph will conform to the United States centers for disease control and prevention's guidelines for water testing for legionella available at https://www.cdc.gov/control-legionella/php/toolkit/routine-testing-module.html and https://www.cdc.gov/investigate-legionella/media/pdfs/cdc-sampling-procedure.pdf. Samples collected may be less than one liter in volume. Collected samples are to be analyzed at a laboratory that has been accredited by a national or international accrediting body according to national or international recognized standards, that has legionella culture testing included in the laboratory's scope of accreditation.

(4) As it relates to waterborne pathogens, coordinate with the Ohio department of health and the local health district having jurisdiction when there is a legionellosis presumptive healthcare-associated case, there are two or more legionellosis possible healthcare-associated cases in a twelve-month period, or when a legionellosis outbreak occurs. When an investigation is required, investigation activities are coordinated with the disease surveillance and recommendations in the Ohio department of health's "Infectious Disease Control Manual", available online at https://odh.ohio.gov/know-our-programs/infectious-disease-control-manual, the CDC guidance on

defining healthcare-associated cases available at https://www.cdc.gov/investigate-legionella/php/healthcare-resources/healthcare-facilities.html, and CDC guidance on conducting investigations available at https://www.cdc.gov/investigate-legionella/php/healthcare-resources/testing-collecting-specimens.html, and includes any or all of the following:

(a) Implementing water use restrictions and/or installation of absolute 0.2 micron biological United States food and drug administration-approved point of use filters on potable hot water fixtures throughout the facility as appropriate or where separate water loops are present and can be isolated within the facility, in locations where the legionellosis case or cases resided, or received treatment or services while in the facility, or otherwise may have been exposed to aerosols from the hot water system or other water features. A hospital with a continuous secondary disinfection system that has demonstrated detections of less than one cfu/ml of legionella through validation testing and control measures specified in the water management plan, may, after consultation of the Ohio department of health and the local health district having jurisdiction, avoid installation of point of use water filters;

(b) Conducting or updating an environmental facility assessment using the United States centers for disease control and prevention's "Legionella Environmental Assessment Form", available online at https://www.cdc.gov/legionella/downloads/legionella-environmental-assessment-p.pdf, or equivalent assessment, for the facility to identify risk conditions that may promote the growth of Legionella or other waterborne pathogens;

(c) Providing a copy of the water management program and at least one year of prior validation testing results to the Ohio department of health and the health district having jurisdiction;

(d) Identification and collection of a set of water samples that is representative of all potable water loops and water sources associated with the investigation, including but not limited to cooling towers, therapy spas, decorative fountains or water features where exposure to aerosols may occur. Water sample testing includes:

(i) At least one cold water sample will be obtained from the incoming water mains from the public water system or the water source;

(ii) Representative samples obtained from a minimum of distal and proximal locations on each floor

of each hot water loop on the hot water distribution system, including hot water storage tanks or storage units when present, both a swab or first draw sample, and a bulk water sample from the fixture or location;

(iii) A sample or samples from locations in the hot water system or water features where the legionellosis case or cases resided, or received treatment or services while in the facility, or otherwise may have been exposed to aerosols from the hot water system or other water features;

(iv) Measurement of total and free chlorine residual, as appropriate, at the time of sample collection, and the observed sustained maximum temperatures for cold and hot water samples.

(v) Preservation and provision of all cultured water and swab samples with observed Legionella cultures that were collected during an investigation of a case or outbreak to the Ohio department of health's public health laboratory for potential comparison against clinically cultured samples.

(e) Collection of water samples under this paragraph will conform to the United States centers for disease control and prevention's "Sampling Procedure and Potential Sampling Sites for Investigation" available at https://www.cdc.gov/legionella/downloads/cdc-sampling-procedure.pdf, to include collection of one liter samples, and "CDC Laboratory Guidance for Processing Environmental Samples" (2005), respectively, with collected samples to be analyzed at a laboratory that has been accredited by a national or international accrediting body according to national or international recognized standards, that has legionella culture testing included in the laboratory's scope of accreditation, and that has demonstrated proficiency in the detection of legionella culture in accordance with the United States centers for disease control and prevention environmental legionella isolation techniques evaluation program.

(f) Implementation of identified actions to correct the risk conditions identified as part of the environmental facility assessment, and environmental water testing results, which may include but not be limited to:

(i) Adjustments to hot water temperatures in storage tanks or circulation systems;

(ii) Correction of areas of poor water flow or stagnation;

(iii) Conducting short-term remediation; or

(iv) Installing permanent disinfection systems;

(g) Provision of appropriate communications to patients, employees, and visitors regarding the investigative and corrective actions to help reduce risk of further exposures;

(h) After remediation actions are completed, or permanent disinfection is installed, collection of the same sample locations and types as set forth in paragraph (K)(4)(d) of this rule as follows:

(i) The first sample set, no earlier than 48 hours after remediation actions have ceased; and

(ii) For the second and subsequent sample sets, no earlier than ten days having elapsed since the last sample collection date;

All sample results collected under this paragraph are to be reported to both the Ohio department of health and the local health district having jurisdiction.

(i) Obtaining the concurrence of the Ohio Department of Health and the local health district having jurisdiction, before lifting of water restrictions or removal of point of use water filters from fixtures when all water or swab samples have legionella detections of less than one colony forming unit per milliliter for potable water

(j) Flushing of all hot water distribution systems and fixtures after water restrictions are lifted and/or point of use water filters are removed; and

(k) An investigation conducted under this paragraph includes revising the hospital's water management program based on the full investigations results and the recommendations of the Ohio Department of Health and the local health district.

(L) Discharge planning, in accordance with 42 CFR 482.43; and

(M) Organ, tissue, and eye procurement, in accordance with 42 CFR 482.45.