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The Hospital + Healthsystem
Association of Pennsylvania
Leading for Better Health

September 25, 2017

Mr. Patrick McDonnell, Chairperson
Environmental Quality Board
Rachel Carson State Office Building, 16 Floor
400 Market Street
Harrisburg, PA 17101-2301

RE: Proposed Rulemaking Amending 25 Pa. Code, Chapter 109—Safe Drinking Water

Dear Mr. McDonnell:

The Hospital and Healthsystem Association of Pennsylvania (HAP)—representing 240 member hospitals and health systems—and the Pennsylvania Society of Health Facility Engineers (PSHFE) appreciates the opportunity to provide comments to the Environmental Quality Board's proposed rulemaking regarding safe drinking water.

Pennsylvania health care facilities are dedicated to providing safe, high quality care to the patients they serve. A health care facility's portable water supply is provided by a public water utility. Many health care facilities consider providing supplemental disinfection to the health care facility's water supply to provide additional protections for its patients and employees at their facility.

Under current Department of Environmental Protection (DEP) regulations, it appears that DEP's interpretation is the a health care facility may be classified as a consecutive public water system, which requires the health care facility to obtain a public water supply permit, conduct routine water quality sampling, and provide notification to a health care facility's community when the system does not meet certain operational criteria. Unfortunately, this interpretation does not take into account the unique circumstances that occur in the health care facility setting, which places an undue regulatory burden upon hospitals.

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It is worth noting that the United States Environmental Protection Agency (EPA) has ruled that states have a wide discretion to implement monitoring modifications for water systems that purchase water from another public water system.

In the EPA policy guidance regarding the interpretation of the Safe Drinking Water Act and regulations, the EPA noted that schools (like hospitals) often install devices to improve the quality of the water, and that if these buildings are considered public water systems subject to all the regulations, the regulatory requirements would both discourage systems from trying to improve the quality of their water and place great burden on states, who would be responsible for overseeing all of the systems. The guidance also noted that States "have the flexibility to modify the monitoring requirements to the extent that the interconnection of the systems justifies treating them as a single system."

In a previous meeting with DEP, we spoke about the unique circumstances health care facilities face when considering the installation of supplemental disinfection systems as they relate to current DEP regulations. We recommended that the current interpretation be revised to exempt hospitals from these requirements or, in the alternative, that DEP implement a process that would allow health care facilities to seek an exemption from certain sections of DEP's regulations related to supplemental disinfection utilization or create a new category of secondary water systems that would address specific health care facility circumstances. We urge the DEP to take advantage of the proposed rulemaking process to consider hospital water systems that purchase water from a public water system as a "single system"—therefore exempting them from unnecessary and undue regulatory burdens, which would be consistent with the guidance provided by the EPA.

To the extent that DEP is unable or unwilling to take this step, we ask that DEP allow hospitals to take advantage of the general permit process outlined in the proposed rule to specifically address a health care facility's unique circumstances related to the implementation of supplemental disinfection to the health care facility's water supply.

This regulatory flexibility is now more important and justified than ever, as a recent policy document from the Centers for Medicare & Medicaid Services (CMS) mandates that all hospitals that participate in the Medicaid or Medicare programs implement a Water Management Program to reduce *Legionella* risk in health care water systems. CMS surveyors conduct on-site surveys to verify compliance. Depending upon the circumstance, these programs may require control measures such as temperature management, visual inspections, and/or a secondary treatment system.

HAP and PSHFE welcome the opportunity to collaborate with DEP to design a general permit process for the implementation of supplemental disinfection systems for health care facilities that recognizes that hospitals are taking steps to improve the quality of the water, and alleviate existing regulatory burdens.

We appreciate the opportunity to share our comments with you. We look forward to working with you to develop a process that will specifically address the hospital community's needs.

Thank you.

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Senior Vice President
Health Economics and Policy

Dan Robison
President

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DEPARTMENT OF HEALTH & HUMAN SERVICES
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-30-*Hospitals/CAHs/NHs*
REVISED 06.09.20

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)
****Revised to Clarify Provider Types Affected****

Memorandum Summary

- ***Legionella* Infections:** The bacterium *Legionella* can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.
- **Facility Requirements to Prevent Legionella Infections:** Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of *legionella* and other opportunistic pathogens in water.
- *This policy memorandum applies to Hospitals, Critical Access Hospitals (CAHs) and Long-Term Care (LTC). However, this policy memorandum is also intended to provide general awareness for all healthcare organizations.*

Background

LD, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium *Legionella*. In a recent review of LD outbreaks in the United States occurring in 2000–2014, 19% of outbreaks were associated with long-term care facilities and 15% with hospitals. The rate of reported cases of legionellosis, which comprises both LD and Pontiac fever (a milder, self-limited, influenza-like illness) has increased 286% in the US during 2000–2014, with approximately 5,000 cases reported to the Centers for Disease Control and Prevention (CDC) in 2014. Approximately 9% of reported legionellosis cases are fatal.

The Centers for Medicare & Medicaid Service (CMS) is aware of multiple recent LD outbreaks in hospitals and long-term care facilities as reported by the CDC, state and local health departments, or investigated by State Survey Agencies (SA).

Outbreaks generally are linked to environmental reservoirs in large or complex water systems, including those found in healthcare facilities such as hospitals and long-term care facilities. Transmission from these water systems to humans requires aerosol generation, as can occur from

showerheads, cooling towers, hot tubs, and decorative fountains. *Legionella* is less commonly spread by aspiration of drinking water or ice. Only one case of possible person-to-person transmission has been reported.

In manmade water systems, *Legionella* can grow and spread to susceptible hosts, such as persons who are at least 50 years old, smokers, and those with underlying medical conditions such as chronic lung disease or immunosuppression. *Legionella* can grow in parts of building water systems that are continually wet, and certain devices can spread contaminated water droplets via aerosolization. Examples of these system components and devices include:

- Hot and cold water storage tanks
- Water heaters
- Water-hammer arrestors
- Pipes, valves, and fittings
- Expansion tanks
- Water filters
- Electronic and manual faucets
- Aerators
- Faucet flow restrictors
- Showerheads and hoses
- Centrally-installed misters, atomizers, air washers, and humidifiers
- Nonsteam aerosol-generating humidifiers
- Eyewash stations
- Ice machines
- Hot tubs/saunas
- Decorative fountains
- Cooling towers
- Medical devices (such as CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units)

CMS Regulatory Authorities

Pertinent regulations include, but are not limited to, the following:

42 CFR §482.42 for hospitals:
"The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases."

42 CFR §483.80 for skilled nursing facilities and nursing facilities:
"The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections."

42 CFR §485.635(a)(3)(vi) for critical access hospitals (CAHs):
CAH policies must include: "A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel."

Expectations for Healthcare Facilities and Surveyors

CMS expects Medicare certified healthcare facilities to have water management policies and procedures to reduce the risk of growth and spread of *Legionella* and other opportunistic pathogens in building water systems. An industry standard[1] calling for the development and implementation of water management programs in large or complex building water systems to reduce the risk of legionellosis was published in 2015 by American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE). In 2016, the CDC and its partners developed a toolkit to facilitate implementation of this ASHRAE Standard (https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html). Environmental, clinical, and epidemiologic considerations for healthcare facilities are described in this toolkit.

Surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities:

- Conduct a facility risk assessment to identify where *Legionella* and other opportunistic waterborne pathogens (e.g. *Pseudomonas*, *Acinetobacter*, *Burkholderia*, *Stenotrophomonas*, nontuberculous mycobacteria, and fungi) could grow and spread in the facility water system.

- Implement a water management program that considers the ASHRAE industry standard and the CDC toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

- Specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.

Healthcare facilities are expected to comply with CMS requirements to protect the health and safety of its patients. Those facilities unable to demonstrate measures to minimize the risk of LD are at risk of citation for non-compliance with the CMS Conditions of Participation. Accrediting organizations will be surveying healthcare facilities deemed to participate in Medicare for compliance with the requirements listed in this memorandum, as well, and will cite non-compliance accordingly.

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[1] ASHRAE 188 *Legionellosis: Risk Management for Building Water Systems* June 26, 2015. ASHRAE: Atlanta. www.ashrae.org

Contact: For questions or concerns regarding this policy memorandum, please contact Dr. Daniel Schwartz at Daniel.schwartz2@cms.hhs.gov.

Effective Date: Immediately. This guidance should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
GUIDANCE FROM HOTLINE COMPENDIUM

WSG H26

SUBJECT: Treatment Facilities as Public Water Suppliers

SOURCE: Betsy Devlin

Title 40 CFR Section 141.3 establishes the coverage and scope of the National Primary Drinking Water Regulations (NPDWRs). This section lists four conditions which a public water system—as defined in Section 141.2 (as amended by the Primacy Rule [63 FR 23361, April 28, 1998])—must meet in order to qualify for exclusion from the NPDWRs. One of the four conditions states that a water system must consist [141.3(a)] "...only of distribution and storage facilities (and does not have any collection and treatment facilities)" [emphasis added].

Water Supply Guidance No. 37 (December 8, 1976), contains a discussion of the definition of treatment. While this discussion provides a basis for interpreting the term with respect to chemical corrosion control treatment, it does not establish an overall working definition. For example, the discussion does not explicitly state whether "non-chemical" technologies (e.g., physical treatment) are considered to be treatment. In addition, literal interpretation of the definition would classify typical point-of-entry (POE) systems, such as lime-soda water softeners, as treatment. Is it the intent of EPA to regulate this type of system?

If so, implementing POE methods of corrosion control, discussed in *Lead in Schools' Drinking Water* (EPA 580/9-89-001), would seemingly result in those schools/facilities being classified and therefore regulated as consecutive public water systems.

The existing definition of treatment also appears to be no longer sufficient in addressing potential situations resulting from the recent proliferation of point of use (POU) water treatment systems. For example, if an apartment landlord owns and maintains POU devices in his rental units, is he to be regulated as a public water system?

Response:

Water Supply Guidance No. 8A (December 8, 1976) addressed the question of the definition of treatment and stated that any person (as defined by the SDWA) who adds any chemical to its drinking water supply is a public water system and is covered by the NPDWRs. In coming to this conclusion, the guidance provided useful information on the definition of treatment and treatment facilities.

The standard dictionary definition of "to treat" is "to subject to some agent or action to bring about a particular result." Water can be "treated" with a chemical agent, such as sodium silicate, in order to bring about a reduction in corrosivity.

The addition of such a substance necessarily changes the chemical composition of the water into which it is added. As such, the addition of chemicals into drinking water to reduce corrosivity should be considered "treatment" within the meaning of SDWA, Section 1411(a). The legislative history of Section 1411 makes it clear, moreover, that Congress only intended to exempt those public water systems, such as hotels or trailer parks, which "merely store and distribute water..."

Furthermore, the standard dictionary definition of a "facility" is "something designed to serve a specific function." Presumably, the on-site addition of corrosion-reducing chemicals into a water supply requires devices, holding tanks, or units to regulate the mixture.

Therefore, the addition of corrosion-reducing substances into water supplies presumably requires "treatment facilities" within the meaning of the SDWA.

Generally, the term "treatment facilities" should be interpreted broadly. Otherwise, the unregulated proliferation of individual on-site chemical treatment of drinking water supplied by public water systems could seriously interfere with efficient regulation of the quality of drinking water, contrary to the purpose of the SDWA to regulate all public water systems "to protect health to the maximum extent feasible."

Consistent with this guidance, then, if a building owner or operator installed a point of entry or point of use device, the device would be considered a "treatment facility." Therefore, the building would become a public water system (assuming it met the requirements of the definition; i.e., had at least 15 service connections or regularly served at least 25 individuals) and the building owner/operator would become a supplier of water as defined by the SDWA. The system would be subject to the SDWA and the NPDWRs.

This approach, however, while consistent with existing policy, may result in a large increase in the number of public water systems, especially as many buildings are installing devices to improve the quality of their water; for example, many schools are installing corrosion control to reduce the lead content of their drinking water to help protect the health of the children. If all these buildings become public water systems subject to all the regulations, we may discourage systems from trying to improve the quality of their water. In addition, we would place a great burden on the States who will be responsible for overseeing all these systems.

Therefore, while the systems described above are public water systems subject to the SDWA and the NPDWRs, they nonetheless may be afforded certain monitoring modifications if they are considered a "consecutive" water system. "Consecutive" water systems are water systems that purchase water from another public water system. Under federal regulations at 40 CFR 141.29, States have the flexibility to modify the monitoring requirements to the extent that the interconnection of the systems justifies treating them as a single system. This flexibility allows States considerable discretion to avoid

unnecessary compliance activities.