DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-40-LSC

DATE: **September 25, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Categorical Waiver – Corrugated Medical Tubing

Memorandum Summary

- CMS regulation requires compliance with the 2012 edition of the NFPA Health Care Facilities Code (NFPA 99) for Ambulatory Surgical Centers, Critical Access Hospitals, End-Stage Renal Disease, Hospitals, Inpatient Hospice, Intermediate Care Facilities for Intellectuals with Disabilities, Long-term Care, Programs for All-Inclusive Care of the Elderly, and Religious Nonmedical Health Care Institutions facilities.
- The 2012 NFPA 99 requires medical gas and vacuum system tubing to be rigid copper tubing and does not allow for the use of corrugated medical tubing (CMT).
- In certain applications, the inability to use CMT may be considered an unreasonable hardship as the installation of CMT may be more efficient and economical.
- CMS is issuing a categorical waiver to allow the use of CMT in new and existing health care facilities based on provisions provided in the 2018 NFPA 99.

Background

CMS regulations governing Ambulatory Surgical Centers, Critical Access Hospitals, End-Stage Renal Disease, Hospitals, Inpatient Hospice, Intermediate Care Facilities for Intellectuals with Disabilities, Long-term Care, Programs for All-Inclusive Care of the Elderly, and Religious Nonmedical Health Care Institutions require compliance with the 2012 edition of the National Fire Protection Association (NFPA) Health Care Facilities Code (NFPA 99).

The 2012 NFPA 99 requires medical gas and vacuum system distribution piping to be rigid copper tubing and does not include provisions for corrugated medical tubing (CMT). CMT is flexible copper tubing that is externally coated with non-metallic fire-retardant sheath and is typically provided in lengths longer than rigid tubing, which may make it more efficient and economical to install. The 2018 NFPA 99 added new provisions that allow for the use of CMT.

Discussion

CMS regulation allows for the waiver of specific provisions of the 2012 NFPA 99 where the application would result in unreasonable hardship upon a provider or supplier, but only if the waiver does not adversely affect the health and safety of patients or residents.

The 2012 NFPA 99 does not include provisions for the use of CMT, which may be more efficient and economical to install. This may result in unreasonable hardship upon providers and suppliers. The 2018 NFPA 99 established requirements for the installation, inspection, testing, maintenance, performance, and safe practices for CMT that provide protection from related hazards.

The inability to install CMT may cause unreasonable hardship and a minimum level of protection is achieved based on compliance with provisions in the 2018 NFPA 99, CMS is providing a categorical waiver to allow for the use of CMT in new and existing facilities in accordance with the 2018 NFPA 99, sections 5.1.10, 5.2.10, and 5.3.10.

The NFPA 99 requires the installation of CMT to be made by American Society of Safety Engineers (ASSE) 6010, *Professional Qualifications Standard for Medical Gas Systems Installers*, qualified installers who are experienced in performing such installations. In addition, inspection and testing must be performed on all new piped medical gas and vacuum systems, additions, renovations, temporary installations, or repaired systems to ensure, by a documented process and procedure, that all applicable provisions of the NFPA 99 have been adhered to and system integrity has been achieved or maintained.

Categorical Waiver Process

Providers and suppliers that want to utilize a categorical waiver must formally elect and document their decision. At the survey entrance conference, a provider/supplier that has elected to use a categorical waiver must provide the survey team with their documented decision and verification of compliance with all applicable provisions. It is not acceptable for a facility to notify surveyors of the election to use a categorical waiver after the survey team has issued a citation. The survey team will review the documentation decision to use the categorical waiver and confirm the facility is compliant with all applicable provisions. This will confirm a minimum level of protection is afforded to protect the health and safety of patients and residents, as required by regulation.

If a provider/supplier conforms to the requirements identified for the categorical waiver, it will not be required to request waiver approval from a CMS Location nor will it need to be cited for an associated deficiency in order to implement this categorical waiver.

The elected categorical waiver must be described by the surveyor under Tag K000, and the Form CMS-2786 should be marked as “Facility Meets, Based Upon, 3. Waivers”. If the survey team determines that the provisions required for the categorical waiver are not being met, a deficiency must be cited under the applicable NFPA 99 waiver regulatory standard:

- ASC: §416.44(c)(2)

- CAH: §485.623(e)(2)
- ESRD: §494.60(e)(3)
- RNHCI: §403.745(c)
- Inpatient Hospice: §418.110(e)(2)
- PACE: §460.72(d)(2)
- Hospital: §482.41(c)(2)
- LTC: §483.70(b)(2)
- ICF-IID: §483.470(j)(5)(v)(B)

Contact: QSOG_LifeSafetyCode@cms.hhs.gov for questions and concerns.

Effective Date: Immediately. This policy 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 & Operations Group (SOG) Management