DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-07-Hospital

DATE: **December 20, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital Equipment Maintenance Requirements

Memorandum Summary

- ***S&C 12-07-Hospital Superceded:*** We are updating previously provided guidance to clarify:
  - Hospital facilities, supplies and equipment must be maintained to ensure an acceptable level of safety and quality.
  - A hospital may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel, unless:
    - Other Federal or state law; or hospital Conditions of Participation (CoPs) require adherence to manufacturer's recommendations and/or set specific requirements. For example, all imaging/radiologic equipment must be maintained per manufacturer's recommendations; or
    - The equipment is a medical laser device; or
    - New equipment without a sufficient amount of maintenance history has been acquired.
- Hospitals electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their Alternate Equipment Management (AEM) program. They must adhere strictly to the AEM activities and/or frequencies they establish.

A. Background

42 CFR 482.41(c) requires that hospitals must maintain adequate facilities for their services and that hospital facilities, supplies, and equipment be maintained to ensure an acceptable level of safety and quality. This memorandum supersedes S&C 12-07-Hospital, issued December 2, 2011, and updates the guidance in Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals," of the State Operations Manual related to hospital facility and

medical equipment maintenance. Facility equipment refers to devices intended to support the physical environment of the hospital. Medical equipment refers to devices intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient by a hospital.

Hospitals comply with this regulation when they perform equipment maintenance in accordance with the manufacturer's recommendations. In such cases, the hospital is expected to maintain documentation of the manufacturer's recommendations as well as of the hospital's maintenance activities.

B. Alternative Equipment Maintenance Frequency or Activities

Under certain circumstances it also may be consistent with the regulatory requirements for a hospital to use maintenance activities or frequency of facility or medical equipment which may not be the same as those recommended by the manufacturer. Hospitals may find that manufacturer's recommendations for some equipment are not available to them or their contractors, or they may through experience have identified more efficient or effective maintenance activities which do not reduce the safety of the equipment.

Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of standards for a medical equipment program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/(R) 2008, *Recommended Practice for a Medical Equipment Management Program*. Likewise an example of written guidelines for physical plant equipment maintenance may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: *Maintenance Management for Health Care Facilities*. The Centers for Medicare & Medicaid Services (CMS) welcomes identification of other recognized sources of recommendations for facility and equipment maintenance.

C. Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance in an alternate manner must be made by qualified personnel, regardless of whether they are hospital employees or contractors. The attached draft guidance provides more details related to qualifications.

In determining whether or not it is safe to include equipment in the AEM program, the hospital must take into account the typical health and safety risks associated with the equipment's use. A hospital is expected to identify any equipment in its AEM program which is "critical equipment," i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. The guidance in Appendix A discusses the types of factors to be considered when hospitals make these determinations. Generally, multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. Note that the risk

may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.
Surveyors must focus their review of a hospital's AEM program on critical equipment in that program and the hospital's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

D. When Equipment is not Eligible for Placement in an AEM Program

- Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the hospital must comply with these other Federal or State requirements, but State Surveyors conducting *Federal* surveys assess compliance only with the federal hospital CoPs.
- Other CoPs require adherence to manufacturer's recommendations and/or set specific standards. For example:
    - The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys.
    - Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.
- The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.
- New equipment for which sufficient maintenance history, either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequency would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the hospital must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.

E. Evaluating Safety and Effectiveness of the AEM Program

The hospital must have policies and procedures which address the effectiveness of the AEM program. In evaluating the effectiveness of the AEM program the hospital is expected to address factors including, but not limited to:

- How incidents of equipment malfunction are identified;

- How incidents of equipment malfunction are investigated, including:
    - Whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and
    - How a determination is made whether or not the malfunction resulted from the use of an AEM strategy;

- The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and

- The use of performance data to determine if modifications in the AEM procedures are required.

The guidance in Appendix A also addresses overall equipment maintenance inventory requirements, as well as AEM program documentation and alternative maintenance strategies.

Questions concerning this memorandum should be addressed to hospitalscg@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management