November 26, 2013

Thomas E. Hamilton
Director, Survey and Certification Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Hamilton:

We are writing to express our concern with the Centers for Medicare and Medicaid Services' (CMS) approach to hospital equipment maintenance as a Condition of Participation. As providers, accreditors, and manufacturers, we represent broad communities with a shared concern in public health and safety. In particular, we believe the interpretive guidance that CMS published on December 2, 2011 appropriately handles the maintenance of equipment used for radiation therapy or medical imaging by categorizing this equipment as "critical to patient health and safety" and requiring the equipment to be maintained according to the manufacturer's methods and frequency. However, we understand that CMS is not enforcing this interpretive guidance and is redrafting it. We ask that the updated interpretive guidance similarly require maintenance according to the manufacturer's recommended standard for medical imaging and radiation therapy equipment.

The 2011 interpretive guidance's approach to medical imaging and radiation therapy equipment maintenance ensures that equipment functions as it was intended with two important consequences. First, medical professionals and equipment users can rely upon the equipment to perform and trust the medical procedure delivered by the equipment is as the user intends. Second, and more importantly, unnecessary risk to patient safety is minimized.

Medical imaging and radiation therapy equipment emit energy and target that energy at the patient's anatomy. These energies are not visible and may include strong magnetic fields, ultrasound waves, and ionizing radiation. Due to the lack of ability to see these forces as they are emitted, users rely on appropriate equipment maintenance and calibration to ensure the equipment functions safely as intended. Without appropriate maintenance, reduced system performance may result in patient or user harm.

Additionally, medical personnel and facilities rely upon medical imaging and radiation therapy equipment to function when needed. These needs include medical emergencies, as is the case with many modalities of medical imaging equipment, or scheduled therapies for critically ill patients, as is the case with radiation therapy. Without appropriate maintenance, reduced system performance may result in downtime, reduced performance quality, and other negative consequences that limit use of the equipment when it is needed. These negative consequences result in barriers to quality patient care and unnecessary delays.

In addition, medical professionals depend on medical imaging and radiation therapy equipment to function as intended. For example, medical professionals expect clinically useful and accurate

image quality from medical imaging equipment. Imaging equipment that is not functioning properly may produce images of reduced quality. With this decrease in quality, the user or medical professional may not immediately recognize that the image does not convey all the information it is capable of conveying had proper maintenance procedures been followed, and the image may be relied upon with a degree of assurance that is misaligned with the performance of the equipment, resulting in a potential missed diagnosis. In another example, medical professionals carefully plan radiation therapy to deliver precise dose to patients at prescribed intervals. Radiation therapy equipment with reduced system performance may not deliver the intended dose to the patient, or may do so to an unintended area of the anatomy.

The recommended maintenance standards developed by medical imaging and radiation therapy equipment manufacturers promote patient and user safety, and support medical professionals in quality patient care. Manufacturers are accountable to the Food and Drug Administration to develop and maintain maintenance standards. We are concerned about any redraft of the 2011 interpretive guidance that would permit deviation from the manufacturer's recommended maintenance standard for equipment used for medical imaging and radiation therapy. As a regulatory authority, CMS is positioned to incentivize practices that promote patient safety and care. This can best be accomplished by ensuring that equipment used for medical imaging and radiation therapy is maintained according to the manufacturer's recommended maintenance standard.

Sincerely,

Advanced Medical Technology Association (AdvaMed)
American Academy of Neurology (AAN)
American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNSF)
American Academy of Oral and Maxillofacial Radiology (AAOMR)
American Association of Oral and Maxillofacial Surgeons (AAOMS)
American Association of Physicists in Medicine (AAPM)
American College of Cardiology (ACC)
American College of Phlebology (ACP)
American College of Radiology (ACR)
American Institute of Ultrasound in Medicine (AIUM)
American Society of Echocardiography (ASE)
American Society of Neuroimaging (ASN)
American Society of Nuclear Cardiology (ASNC)
American Society of Radiologic Technologists (ASRT)
American Venous Forum (AVF)
Intersocietal Accreditation Commission (IAC)
Medical Imaging & Technology Alliance (MITA)
Society for Cardiovascular Angiography and Interventions (SCAI)
Society for Cardiovascular Magnetic Resonance (SCMR)
Society for Clinical Vascular Surgery (SCVS)
Society for Vascular Surgery (SVS)
Society for Vascular Ultrasound (SVU)
Society of Cardiovascular Computed Tomography (SCCT)

Society of Diagnostic Medical Sonography (SDMS)
Society of Interventional Radiology (SIR)
Society of NeuroInterventional Surgery (SNIS)
Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Society of Pediatric Echocardiography (SOPE)
Society of Radiologists in Ultrasound (SRU)
World Molecular Imaging Society (WMIS)

cc: Marilyn Tavenner, Administrator, Centers for Medicare & Medicaid Services
Jonathan Blum, Principal Deputy Administrator, Centers for Medicare & Medicaid Services
Patrick Conway, MD, Chief Medical Officer, Director, Office of Clinical Quality and Standards, Centers for Medicare & Medicaid Services