MITA®
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

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BY ELECTRONIC DELIVERY

Thomas Hamilton
Director, Survey and Certification Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

Re: Meeting with CT Stakeholders to Discuss Determination and Documentation of Compliance with NEMA XR-29 Standard

Dear Mr. Hamilton:

The Medical Imaging & Technology Alliance (MITA) greatly appreciates all of the effort that has gone into on-time implementation of the new quality incentives for computed tomography (CT) services, as directed by Section 218(a)(1) of the Protecting Access to Medicare Act (PAMA). As you know, services performed on CT scanners which are not compliant with the NEMA XR-29 standard saw a reduction in payment beginning on January 1, 2016. As compliance auditing of CT devices moves forward, MITA would like to be a constructive partner in helping CMS determine appropriate compliance measures. This letter outlines our questions on the process that CMS will use to determine compliance.

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The MITA CT Group hosted a CT stakeholder meeting on December 1st at the Radiological Society of North America's (RSNA) annual meeting. The stakeholders present represented radiologists, hospital administrators, medical physicists, and individual institutions. During this meeting, there was extensive discussion concerning the misinformation, confusion, and uncertainty regarding the determination and documentation of compliance to the NEMA XR-29 "Standard Attributes on CT Equipment Related to Dose Optimization and Management" (MITA SmartDose) Standard.

There is ongoing uncertainty as to how compliance with XR-29 will be determined, particularly with regard to acceptable documentation of compliance. Providers are deeply concerned, particularly given the payment reductions they will see if their CT systems are non-compliant.

Of significant concern is the fact that multiple third-party vendors are claiming "XR-29 Solutions" which, despite their marketing claims, may or may not actually upgrade a CT scanner to full compliance with the law. We are deeply troubled that some health care providers are being misled and that these third-party products in fact change the manufacturer's specifications, thereby "adulterating" imaging equipment in ways which may present serious harm to patients - unless the third party solution is qualified as compatible by the OEM CT manufacturer.

MITA is in a unique position given its in-depth understanding of XR-29 as well as the collective knowledge of its member companies as to the compliance of each of their CT systems in the field. The attributes necessary for compliance with XR-29 are either included with the CT system at time of manufacture or, in many cases, have been subsequently added by the manufacturer as part of a field upgrade.

Stakeholders have many questions that remain unanswered and we would greatly appreciate a response:

- How are the reimbursement changes for CT services being communicated to providers such that billing and coding processes can differentiate services performed on compliant and non-compliant systems?
- How will CMS determine if diagnostic CT services from a particular scanner are subject to the lower payment rate?
- When should facilities expect their first audit of CMS billings of diagnostic CT services under the new law, and will this be performed in conjunction with an accreditation survey from an approved national accrediting organization?
- What are the consequences of not applying the modifier code for services performed on a non-qualifying CT system?
- Does CMS intend to rely on: the CT system manufacturer-supplied XR-29 conformance certificates; certificates from the vendors of add-on "XR-29 Solutions" for their associated attributes; or on-site evaluation of CT systems to determine compliance?
- Do the accrediting organizations have adequate technical knowledge and sufficient training to determine a CT system's compliance to the four attributes required by the XR-29 standard?

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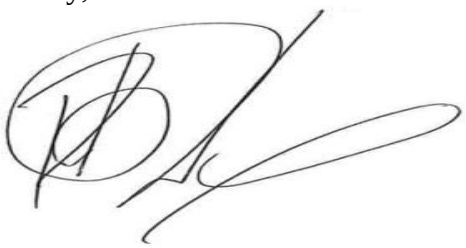
MITA will be in touch with your office soon to arrange an in-person meeting to discuss these issues. In the meantime please let us know if you have any questions and how we can assist you.

Sincerely,



Peter Weems
Director of Policy and Strategy, MITA

MITA is the collective voice of medical imaging equipment, radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.