DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

MAR 0 4 2016

Peter Weems
Director of Policy and Strategy
MITA
1300 North 17th Street, Suite 900
Arlington, VA 22209

Dear Mr. Weems:

Thank you for your correspondence regarding the questions posed at your meeting with Computed Tomography Stakeholders to discuss determination and documentation of Compliance with the NEMA XR-29 Standard. The Centers for Medicare & Medicaid Services (CMS) appreciates your support of the 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).

We have enclosed specific answers to your questions and hope the answers address your concerns.

Sincerely,

Thomas E. Hamilton

Enclosure

Enclosure

CMS Responses to Questions Submitted By Medical Imaging Technology & Alliance (MITA):

Q1: 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?

A1: The information about the requirements mandated by §218(a) of PAMA has been published in several forums that are readily available to the public and stakeholders, including but not limited to:

- Publication of the PAMA Act legislation on the GPO.gov website.
- Publication of the OPPS/ASC proposed rule in the Federal Register on 07/08/2015, in which CMS proposed to implement the requirements mandated by §218(a) of PAMA (80 FR 39300).
- Solicitation of public comments in response to CMS' proposals for implementation of the requirements mandated by §218(a) of PAMA from 07/08/15 to 09/08/15.
- Publication of the OPPS/ASC final rule in the Federal Register on 11/13/2015, in which CMS finalized the proposals to implement the requirements mandated by §218(a) of PAMA (80 FR 70470).
- Publication of the Physicians Fee Schedule proposed rule in the Federal Register on 07/15/2015, in which CMS proposed to implement the requirements mandated by §218(a) of PAMA (80 FR 41716).
- Solicitation of public comments in response to our proposals for implementation of the requirements mandated by §218(a) of PAMA from 07/15/15 to 09/15/15.
- Publication of the Physicians Fee Schedule final rule in the Federal Register on 11/15/2015, in which CMS finalized the proposals to implement the requirements mandated by §218(a) of PAMA rule that was published in the Federal Register on 07/15/2015 (80 FR 70930).
- The January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) (Change Request 9486, Transmittal 3425).

In addition to the published materials as outlined above, a Hospital Open Door Forum was held on 1/26/16.

Q2: How will CMS determine if diagnostic CT services from a particular scanner are subject to the lower payment rate?

A2: Section 218(a) of the PAMA legislation amended §1834 of the Social Security Act (the Act) by establishing a new subsection 1834(p), titled "Quality Incentives to Promote Patient Safety and Public Health in Computed Tomography." The subsection reduces payment under the

OPPS for hospital outpatient radiology providers and the Physicians Fee Schedule (PFS) for ADI suppliers by 5 % in 2016 and 15 % in 2017 and all subsequent years for applicable CT services. Section 1834(p)(2) defines the CT services subject to the payment reduction for services furnished using equipment that do not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013 by certain CPT HCPCS codes. Section 1834(p)(2) of the Act lists the particular HCPS procedure codes for CT services for which the payment modifier must be used when performed using non NEMA XR-29 CT equipment:

Section 1834(p)(2) of the Act states the following:

> *"the term 'applicable computed tomography service' means a service billed using diagnostic radiological imaging codes for computed tomography (identified H. R. 4302—25 as of January 1, 2014, by HCPCS codes 70450–70498, 71250– 71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes)."*

Applicable ADI provider and suppliers should use the payment modifier for the CT services billed under the above-listed HCPS codes or any succeeding codes.

Q3: 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?

A3: The accrediting organizations will only be evaluating compliance with the NEMA XR-29 on a periodic basis. They will not be auditing billings submitted by providers to determine if non-compliant ADI providers/suppliers have used the payment modifier. At this time, we do not know when the first billing audit will be conducted.

Q4: What are the consequences of not applying the modifier code for services performed on a non-qualifying CT system?

A4: Pursuant to §218(a) of the Protecting Access to Medicare Act (PAMA) and a final rule titled *"Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule,"* effective January 1, 2016, hospital outpatient radiology departments and ADI suppliers must perform CT procedures with CT equipment that meet the NEMA XR-29 safety standards. If hospital outpatient radiology departments and ADI suppliers use CT equipment that does not meet NEMA XR-29 safety

standards they will receive a reduction in their Medicare payments for services provided with the non-compliant CT equipment in the amount of 5% in calendar year 2016. This payment reduction will increase to 15% in calendar year 2017 and each year thereafter.

The CMS payment staff are currently developing a process should a hospital outpatient radiology department or ADI supplier bill Medicare for CT procedures performed using equipment that does not meet the NEMA XR-29 standards but does not use the payment modifier on their billing.

Q5: 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?

A5: CMS will accept manufacturer certification of XR-29 conformance of CT equipment. We believe that these certificates will provide reliable evidence of compliance of with the requirements of §218 of PAMA and §1834(p) of the Act.

An ADI provider must provide documentation of a certificate for each piece of CT equipment. There are two options for evidence. An ADI provider may provide one certificate for each piece of CT equipment located within their facility and all other locations. Each certificate must include the unique CT system number for each CT system. Or an ADI provider may produce one certificate of compliance for all its CT systems. The single certificate must specifically list each individual CT system and its unique CT system identifier.

Q6: 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?

A6: The accrediting organizations (AOs) will not be required to assess technical and mechanical with NEMA XR-29 compliance of the CT systems. The AOs will be tasked with obtaining proof of compliance in the form of a manufacture's certification of NEMA XR-29 compliance.