



Center for Clinical Standards and Quality/Survey & Certification Group

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DATE: April 8, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Computed Tomography (CT) Compliance Clarifications under Section 218(a)(1)
of the Protecting Access to Medicare Act (PAMA)- Information Only

***** Revised to clarify questions regarding oversight *****

Memorandum Summary

- **Information Only:** The Centers for Medicare & Medicaid Services (CMS) is sharing this clarification with State and Federal Surveyors as information only. Surveyors will not be expected to determine compliance with Advanced Diagnostic Imaging (ADI) **suppliers or hospital outpatient department** requirements. **Accrediting Organizations (AOs) will be evaluating compliance on a periodic basis. State Agency and Regional Office Staffs have no role to play in this process.**
- **Clarifications:** The CMS is providing compliance and payment clarifications based on stakeholder questions regarding National Electrical Manufacturers Association (NEMA) XR-29 Standard.
- **Frequently Asked Questions (FAQs):** The FAQs attached with this policy memorandum aim to clarify stakeholder uncertainty and to include aspects of payment reductions if CT systems are found non-compliant.

Background

The Protecting Access to Medicare Act (H.R. 4302; P.L. 113-93), also known as PAMA, enacted in 2014, amended the Social Security Act (the Act) to extend Medicare payments to physicians and other providers of the Medicare and Medicaid program.

Section 218(a) of the Protecting Access to Medicare Act (PAMA) requires that ADI suppliers and hospital outpatient areas providing CT services must meet safety requirements under NEMA Standard XR-29-2013 beginning on January 1, 2016. ADI suppliers and hospital outpatient departments that are non-compliant with these safety requirements must use a Current Procedural

Terminology (CPT) code modifier on their Medicare billing to attest to non-compliance. These non-compliant ADI suppliers will receive a decrease in their Medicare payment of 5% in 2016 with a further reduction to 15% in 2017 and thereafter.

Clarification

In late 2015, stakeholders which included radiologists, hospital administrators, medical physicists, and individual institutions raised concern regarding the uncertainty of determination and documentation of compliance to the NEMA XR-29 “Standard Attributes on CT Equipment Related to Dose Optimization and Management” (MITA SmartDose) Standard.

Additionally, third party vendor claims of “XR-29 Solutions” may or may not actually upgrade a CT scanner to full compliance within the law has raised concern among the health care industry.

Therefore, CMS has compiled the attached FAQ document to clarify reimbursement changes for non-compliant systems and information regarding billing, coding and payment rates.

Effective Date: This memorandum is provided as information only. If providers have questions about this topic, they should be referred to this email box: ADIAccreditation@cms.hhs.gov.

/s/

Thomas E. Hamilton

Attachment: Frequently Asked Questions Regarding Compliance to section 218(a)(1) of PAMA

cc: Survey and Certification Regional Office Management

Frequently Asked Questions Regarding Compliance to section 218(a)(1) of PAMA

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 Outpatient Prospective Payment System (OPPS)/ Ambulatory Surgical Center (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 OPPTS/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 (PFS) 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 PFS 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 OPPTS (Change Request 9486, Transmittal 3425).

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 OPPTS for hospital outpatient radiology providers and the 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 Current Procedural Terminology (CPT) Healthcare Common Procedure Coding System (HCPS) 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 (AOs) 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 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.

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 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.

Q7: What role will the Regional Office and State Agency staffs play in this process?

A7: Regional Office and State Agency staffs have no role to play in this process.