The American College of Radiology NEMA XR-29 (MITA Smart Dose) Standard: Frequently Asked Questions

(Revised: June 26, 2018; updated guestions in red)

The Protecting Access to Medicare Act (PAMA) signed into law in April 2014 was the last "patch" of the SGR and included many implications for imaging providers. Among these are requirements that health care providers comply with the National Electrical Manufacturers Association (NEMA) XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management (also known as MITA Smart Dose) for full reimbursement. The final rule was published at the end of October 2015 and went into effect on January 1, 2016.

The following Frequently Asked Questions contain information from the law and federal regulations but does not constitute ACR "guidance."

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General

1. Q. What is XR-29?

- A. The NEMA XR-29 standard (MITA Smart Dose) specifies four attributes of CT scanners that "contribute to or help perform optimization and or management of doses of ionizing radiation while still enabling the system to deliver the diagnostic image quality needed by the physician." CT scanners meeting the XR-29 Standard have the following:
 - DICOM-compliant radiation dose structured reporting. See <u>NEMA XR 29-2013</u> (Standard Attributes on CT Equipment Related to Dose Optimization and Management) and http://dicom.nema.org/.
 - Dose check features. See NEMA XR 25-2010 (Computed Tomography Dose Check).
 - Automatic exposure control. See <u>NEMA XR-28-2013</u> (Supplemental Requirements for User Information and System Function Related to Dose in CT).
 - Reference adult and pediatric protocols. See <u>NEMA XR-28-2013</u> (Supplemental Requirements for User Information and System Function Related to Dose in CT).

2. Q. What is the law that calls for compliance with XR-29?

A. Protecting Access to Medicare Act (PAMA) of 2014

3. Q. What is the CMS final rule (2016 MPFS) regarding XR-29?

A. CMS requires the following:

"Beginning January 1, 2016, hospitals and suppliers will be required to report the modifier "CT" on claims for CT scans described by any of the CPT® codes identified in this section (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scanners. The use of this modifier will result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act."

Search on "XR-29" in the CMS document below to find the relevant rule and their response to public comments:

- Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 Medicare Physician Fee Schedule (https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-28005.pdf)
- 4. Q. I have questions regarding CMS's requirements for CT scanner compliance with XR-29 and reimbursement. How do I contact CMS?
 - A. See the CMS FAQs included in their <u>April 8, 2016 memo</u> to State Survey Agency directors. You may also contact CMS at <u>ADIAccreditation@cms.hhs.gov</u>.

Applicability and Reimbursement

- 1. Q. What are the penalties for non-compliance with XR-29?
 - A. Effective January 1, 2017, CT equipment not in compliance with all four attributes of the XR-29 Standard will be subject to a 15 percent per scan technical component reduction. (This is an increase from the 5 percent per scan reduction that was in place on January 1, 2016.)
- 2. Q. Where does the law apply?
 - A. This penalty applies only to the *technical component* [and the technical component of the global fee] on diagnostic CT procedures billed in *imaging centers, physician offices and hospital outpatient settings*. If a facility bills for both inpatient and outpatient CT scans on the same scanner, the reduction applies only to those scans billed as Medicare outpatient procedures. The policy does not affect scans billed under the hospital inpatient setting (including those at *critical access hospitals*).

3. Q. To what procedures does this law apply?

- A. This penalty applies only to the *technical component* and the technical component of the global fee of the following diagnostic CT procedure CPT[®] codes:
 - 70450-70498
 - 71250-71275
 - 72125–72133
 - 72191-72194
 - 73200–73206
 - 73700–73706
 - 74150-74178
 - 74261-74263
 - 75571-75574
 - Any succeeding codes

These are diagnostic CT procedures that include head/brain, abdomen, pelvis, upper extremity, lower extremity, etc. CMS will maintain a list of codes subject to the "CT" modifier in the web supporting files for the annual rule.

4. Q. Does the law apply to interventional radiology procedures on the CT scanner?

A. No, the law does not apply to interventional radiology procedures performed on the CT scanner.

5. Q. Does the law apply to CT simulation for radiation therapy?

A. No, the law does not apply to CT simulation for radiation therapy.

6. Q. Does the law apply to PET/CT procedures?

A. No, the law does not apply to PET/CT procedures. However, if the PET/CT scanner is used for *diagnostic CT studies and includes any of the CPT® codes listed above*, the law does apply.

7. Q. How will imaging facilities be expected to document to CMS that their CT scanners do or do not comply with XR-29?

A. CMS created the modifier "CT" (computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard) to assist practices in identifying noncompliant equipment. The rule specifies that:

"Beginning January 1, 2016, hospitals and suppliers will be required to **report the modifier** "CT" on claims for CT scans described by any of the CPT[®] codes identified in this section (and any successor codes) that are furnished on **non-NEMA Standard XR-29-2013-compliant CT scanners**. The use of this modifier will result in the applicable payment reduction for the CT service." See MLN Matters MM9250 for the official information from CMS.

- 8. Q. How do you add the CT modifier to the technical component for noncompliant CT scanners when the facility bills globally?
 - A. Append the "CT" modifier to the global charge to designate the procedure was performed on equipment that is noncompliant with the NEMA standard. Medicare Administrative Contractors will make the payment adjustment only to the technical component of the global charge.

According to CMS Transmittal #3402:

"Effective for claims with dates of service January 1, 2016, through December 31, 2016, a 5 percent reduction applies to the technical component (and the technical component of the global fee) of the MPFS amount when the CT modifier is billed with the procedure codes...For a global procedure billed with modifier CT, contractors shall reduce the global fee schedule amount by an amount equal to 5 percent of the fee schedule amount for the TC only code."

"Effective for claims with dates of service on or after January 1, 2017, a 15 percent reduction applies to the technical component (and the technical component of the global fee) of the MPFS amount when the CT modifier is billed with the procedure codes...For a global procedure billed with modifier CT, contractors shall reduce the global fee schedule amount by an amount equal to 15 percent of the fee schedule amount for the TC only code."

- Q. What if our facility's equipment is not XR-29 compliant and we do not report modifier "CT?"
 - A. If modifier "CT" is not appropriately assigned on the claim form to designate a procedure performed on equipment not in compliance with XR-29, Medicare will pay the full allowed amount. Once Medicare identifies an overpayment has been made, *the overpayment amount becomes a debt owed to the Federal government*. Civil monetary penalties may apply if you know of an overpayment and do not properly report and return it.
- 10. Q. Our facility has two different CT scanners: one is compliant and one is not upgradable to become compliant. Will reimbursement for all CT scans performed at the facility be reduced or just those specifically performed on the non-complaint scanner?
 - A. Reimbursement will only be reduced for applicable CT examinations performed on the noncompliant CT scanner that are designated by modifier "CT." In order to ensure that only procedures performed on noncompliant units will be marked for reduction, facilities will need to modify their internal procedures so that the correct modifier is submitted for noncompliant machines. In order to receive full reimbursement for all applicable CT exams performed, *all* CT scanners within a facility will need to comply with XR-29.
- 11. Q. If a hospital bills for both outpatient and inpatient CT scans done on a scanner located in the hospital, would the hospital be penalized for both outpatient and inpatient procedures performed on the noncompliant equipment?
 - A. When a hospital bills for both outpatient and inpatient CT scans performed on a scanner located in a hospital, the payment reduction would apply only to those scans billed as outpatient examinations with modifier "CT," regardless of the exact physical location of the CT scanner.

- 12. Q. If a noncompliant CT scanner is replaced in March 2018 with a new, XR-29-compliant scanner, will the facility only receive a 15 percent per scan reduction in reimbursement from January to March 2018?
 - A. Yes. Reimbursement will be reduced by 15 percent per scan for all applicable CT examinations performed on the noncompliant CT scanner from January to March 2018. The facility should receive full reimbursement for applicable CT examinations performed on the new, XR-29-compliant CT scanner after March 2018.
- 13. Q. Can the patient be held responsible for the reduction in payment by Medicare?
 - A. No, the Medicare beneficiary is not liable for the payment reduction applied to procedures performed on noncompliant CT equipment.
- 14. Q. Does the XR-29 penalty affect reimbursement for patients on state Medicaid programs?
 - A. No. XR-29 only applies to Medicare.
- 15. Q. Does ACR know how non-Medicare insurances (e.g., HMOs, PPOs, Medicare Replacement Plans, and commercial) will treat CT scans that are noncompliant with XR-29? Are they planning on following Medicare's lead and lowering reimbursement rates?
 - A. At this time, we are not aware of any commercial plans that are following the XR-29 Medicare mandate. The ACR's Managed Care Network will monitor this and provide information on our website should this change.
- 16. Q. How will noncompliance with XR-29 standards be verified?
 - A. According to the Medicare Claims Processing Manual, Chapter 12 Physician/Nonphysician Practitioners, (issue 1-6-16) 20.4.7:

"The statutory provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard...The statutory provision also provides that such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under SSA section 1834(e) and hospitals under SSA section 1865(a)." (See CMS Transmittal #3402, section 20.4.7.)

- 17. Q. Our facility is accredited in CT with the ACR. How will ACR verify that our CT scanners do or do not comply with the XR-29 standards?
 - A. The statutory provision for XR-29 provides that "such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under SSA section 1834(e) and hospitals under SSA section 1865(a)." (See CMS Transmittal #3402, section 20.4.7.)

In 2017, the ACR requested NEMA XR-29 certificates of compliance from all ADI facilities with accredited CT units. Prior to transmitting NEMA XR-29 non-compliant information to CMS, the ACR is following up with ADI suppliers that have not submitted documentation regarding the NEMA XR-29 compliance status of their CT units as part of the 2017 baseline NEMA XR-29 data collection. All new and existing ADI suppliers will be allowed to submit or update documentation of NEMA XR-29 compliance within the accreditation database.

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During each Validation Survey, ACR surveyors will verify the NEMA XR-29 compliance documentation status for each accredited CT unit owned or operated by the ADI supplier being surveyed. If a CT unit is NEMA XR-29 compliant, the ADI supplier must provide a certificate of NEMA XR-29 compliance (or other acceptable documentation) as evidence of compliance. If any CT unit does not meet the NEMA XR-29 standard, it will be noted in their accreditation file and the ACR will submit information about the non-compliant CT unit to CMS.

18. Q. Must our CT scanner meet the XR-29 standards in order to achieve accreditation with the ACR?

A. No. The ACR does not require that your CT scanner meet the XR-29 standards in order to achieve accreditation. (See the CT Accreditation Program Requirements for complete information on achieving accreditation with the ACR.)

Certificates of NEMA XR-29 Compliance

- 1. Q. Must NEMA XR-29 compliance documentation be in the form of a certificate?
 - A. No, other documentation such as a letter or a report of compliance are also acceptable as long as it contains the information specified below.
- 2. Q. What information must the NEMA XR-29 certificate of compliance (or other acceptable documentation) contain?
 - A. The NEMA XR-29 certificate of compliance (or other acceptable documentation) must include:
 - Date documentation was issued.
 - Name and address of entity providing the documentation.
 - CT unit manufacturer name, model name and serial number.
 - Name of ADI facility and location where the CT unit is installed.
 - A statement that the CT unit fully complies with NEMA XR-29 "Standard Attributes on CT Equipment Related to Dose Optimization and Management". The documentation must specifically state that the equipment complies with the following four NEMA XR-29 attributes and provide a date that compliance of each attribute was met (if compliance of all four attributes were met on the same date, one date is acceptable):
 - DICOM-compliant radiation dose structured reporting
 - Dose check features (NEMA XR-25)
 - Automatic exposure control (NEMA XR-28)
 - o Reference adult and pediatric protocols (NEMA XR-28)

3. Q. Who may issue the NEMA XR-29 certificate of compliance (or other acceptable documentation)?

- A. NEMA XR-29 certificates of compliance (or other acceptable documentation) may be provided by:
 - The CT unit's original equipment manufacturer (OEM), or
 - A non-OEM entity such as a 3rd party NEMA XR-29 upgrade solution provider, an equipment service provider, or a medical physicist.

Equipment Compliance and Features

- 1. Q. How can I determine if my CT scanner is compliant with XR-29?
 - A. To determine if your CT equipment complies with the NEMA XR-29 standard, please contact your CT scanner's manufacturer. You should also visit your manufacturer's XR-29 Vendor Certification Web Portal on the <u>MITA Smart Dose</u> website to download verification of compliance.
- 2. Q. Our CT scanner meets some but not all of the four XR-29 provisions. Must our scanner meet all of the XR-29 provisions in order to obtain full reimbursement?
 - A. Yes, your scanner must meet all of the following XR-29 provisions in order to obtain full reimbursement:
 - DICOM-compliant radiation dose structured reporting.
 - · Dose check features.
 - Automatic exposure control.
 - Reference adult and pediatric protocols.
- 3. Q. Our CT scanner manufacturer has informed us that they are unable to upgrade our scanner so that it is compliant with XR-29. May we modify our CT scanner with a commercial 3rd party solution to meet XR-29 compliance?
 - A. Yes, as long as the provider can provide a NEMA XR-29 certificate of compliance (or other acceptable documentation).
- 4. Q. Does XR-29 require that the facility use any or all of the XR-29 features (e.g., dose check, automatic exposure control, reference adult and pediatric protocols, etc.) available in the XR-29-compliant CT scanner?
 - A. No. XR-29 only requires that the CT equipment used for applicable examinations be compliant with XR-29. The law does not require facilities to use these features. However, ACR recommends that XR-29 dose optimization features be used as clinically appropriate to optimize radiation dose to the patient.
- 5. Q. Does XR-29 require that the radiation dose from the examination be documented in the patient's final report?
 - A. No. XR-29 does not require facilities to document radiation dose in the patient's final report.
- 6. Q. What agency do we submit the dose report to? Does the report have to come straight from our scanner to a computer?
 - A. There is no requirement to submit a dose report to any federal agency.
- 7. Q. Do we have to have dose monitoring software to keep a cumulative log of each patient's DLP (dose-length product) and CTDI (computed tomography dose index) to meet the CMS requirements?
 - A. No. XR-29 does not require dose monitoring software or keeping "a cumulative log of each patient's DLP and CTDI." Furthermore, the ACR does not recommend adding up DLP and CTDI_{vol} for individual patients since these numbers are not patient dose but

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rather dose indices to plastic phantoms that probably don't mimic the size of the patient that is being examined. Adding up such numbers is especially meaningless if the exams were done on different body regions of the patient.

8. Q. How can I learn more about the XR-29 features of my CT equipment?

A. Contact your manufacturer's representative or applications specialist for details and training on your CT scanner's XR-29 features.

9. Q. How can I better understand XR-29's DICOM-compliant radiation dose structured reporting feature?

A. See "The DICOM Radiation Dose Structured Report: What It Is and What It Is Not" in the Journal of the American College of Radiology.

10. Q. How can I better understand XR-29's Dose Check feature?

A. XR-29's Dose Check feature provides notifications and alerts so that radiologic technologists and physicians are aware of potentially high radiation doses during CT examinations. It is important that staff be aware of the proper use and limitations of these notifications and alerts. The AAPM-ACR-ASRT-MITA FDA Working Group Standardization of CT Nomenclature and Protocols have developed a set of *free*, general and manufacturer-specific educational slides that cover key points to ensure successful implementation of these features. Visit the <u>AAPM CT Scan Protocol</u> website and click on the "CT Dose-Check" tab to view these slides and obtain for more useful information.