ahra
the association for medical imaging management

August 31, 2015

The Honorable Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1633–P
P.O. Box 8010
Baltimore, MD 21244–8010

Dear Acting Administrator Slavitt:

On behalf of AHRA, we are pleased to submit the following comments on the 2016 Medicare Hospital Outpatient Prospective Payment System (OPPS) proposed rule (CMS-1633-P). AHRA: The Association for Medical Imaging Management is the professional organization representing over 5,000 members at all levels of management at 1,800 hospital imaging departments, freestanding imaging centers, and group practices. Collectively, AHRA members employ or supervise over 100,000 radiologic technologists, managers, and administrative staff.

Our comments are focused on two issues:

1. NEMA Standard XR-29
2. Low-Dose CT Lung Cancer Screening billing requirements

1. NEMA Standard XR-29

Section 218 of the Protecting Access to Medicare Act (PAMA) mandates a 5% reduction in the Medicare Part B payment for 2016 and a 15% reduction in the Medicare Part B payment for 2017 and beyond, for the technical component (TC) of certain CT services performed using equipment that does not meet the requirements of the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013 (XR-29). CMS proposes that beginning January 1, 2016, claims for services:

> HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes)

that are furnished using non-XR-29 compliant equipment will result in the applicable payment reduction for the service.

To implement this provision, CMS is proposing creation of a modifier code that would be appended to claims for the above services when the equipment DOES NOT meet the XR-29 standards.

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Recommendation

Although AHRA supports the goal of Section 218, the myriad operational, financial and system changes (outlined below) required for imaging departments to meet the January 1, 2016 deadline, are such that **we respectfully request a one-year delay in the enforcement of this provision.** This delay would allow sufficient time for imaging departments/facilities to ensure compliance with the XR-29 standards by the new deadline. It will also provide additional time to address internal operational challenges presented by the need to identify compliant vs. non-compliant CT equipment.

Discussion

AHRA supports the goal of ensuring that Medicare beneficiaries have access to the safest, most efficient CT equipment available.

Unfortunately, the timetable mandated by Congress is unreasonable. Although tremendous progress has been (and will continue to be) made on upgrading CT equipment, based upon our industry assessment, hundreds of hospitals will still have at least one piece of non-compliant CT equipment in service after the January 1 effective date.

In late July, AHRA conducted an XR-29 readiness survey (results attached) assessing the readiness of our members. We received approximately 500 responses to this survey. Responses came from institutions of all sizes and most maintained multiple pieces of CT equipment.

Currently only 44% of our members report that all of their CT equipment is XR – 29 compliant. Most imaging facility administrators reported a mixture of compliant and non-compliant equipment. Although the current level of adherence is relatively low, most Administrators (64%) believe that ALL of their equipment will be XR-29 compliant by January 1, 2016. Unfortunately, this also means that 36% will have at least one non-compliant CT scanner as of January 1, 2016.

CMS should understand that when a patient presents to the imaging department for a CT scan, the requisition or order for the radiology service does not always connote that the patient's care is covered by Medicare, commercial insurance, Medicaid or no insurance. The technologists performing the scan does not usually know the type of insurance coverage a particular patient might have at that point in time. Therefore, even though the XR-29 policy only applies to outpatient Medicare patients, the imaging department will need to set up a process for documenting the use of XR-29 compliant vs. non-compliant equipment for ALL patients, regardless of payer.

As noted above, most imaging departments have multiple CT scanners in use and for a significant percentage of departments, they will have a mixture of compliant and non-compliant equipment.

Establishing an internal process for identifying patient-specific use of XR-29 compliant equipment vs. non-compliant equipment is extremely challenging.

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Furthermore, communicating patient-specific, machine-specific information to the billing staff creates tremendous administrative and operational challenges for radiology and billing departments. For many organizations, the only way to effectively communicate this information to the billing department is to create a duplicate Charge Description Master (CDM) for use by the technologist performing the CT scan. In some organizations there will be additional programming required in the Radiology Information System (RIS) to map the new CDM options appropriately. Duplicating a CDM and making revisions to the RIS can be a lengthy process, especially when internal IT and financial resources are already dedicated to other regulatory mandated issues such as ICD-10 implementation. As such, the time required to make the changes needed to comply, make the January 1, 2016 effective date unrealistic.

Additionally, asking the technologist who is performing the imaging procedure to distinguish different codes in the RIS and/or CDM based on the equipment to be sent to the billing department is labor-intensive, and opens the possibility for inadvertent errors. These workaround processes will be inefficient, costly and add unnecessary administrative burden on imaging departments unless CMS chooses to delay their enforcement of the NEMA/XR-29 standards until January 1, 2017.

By allowing additional time for imaging departments to become 100% compliant with the XR-29 standards, we can minimize the number of Departments that will have to undertake the workaround processes described above.

Capital Requirements/Resource Use

Although the mandatory use of XR-29 compliant CT equipment was adopted in April, 2014, the exact method to communicate compliance or non-compliance was not defined until recently. As such, the amount of time provided to implement the necessary changes was unreasonable for the operational reasons already stated. But even if the operational challenges outlined above were easily resolved, this would still not address an even more significant issue – the availability of the capital necessary to make the XR-29 upgrades and, in some states, completing the state mandated Certificate of Need (CON) reviews (where applicable) that could be triggered by the purchase of new equipment.

Most hospital capital budgets are set well in advance – in some cases 2-years in advance – of when a particular project or purchase will occur. Depending upon the age of a hospitals CT equipment, meeting the XR-29 standards could range from the need to purchase new equipment costing millions of dollars to "upgrading" existing equipment at a cost of several hundred thousands of dollars. The capital requirements either way are significant. As you know, hospital capital budgets have been taxed these past few years attempting to meet the federal EHR and ICD-10 requirements.

Furthermore, depending upon the state, the purchase of new equipment can sometimes trigger a CON review to justify the capital expenditure. Filing the necessary paperwork and going through the public hearing process can sometimes take months to complete.

Finally, in the event a hospital/imaging department needs to purchase new equipment, it is not simply a case of opening a catalog and ordering a new CT scanner for delivery next week by UPS. New equipment often requires physical infrastructure changes including upgraded HVAC and mechanical/electrical changes. These upgrades consume capital resources (both time and money) which must be budgeted.

Undertaking this change at a time when hospital capital budgets are already being strained by other demands is unreasonable. Therefore, AHRA recommends that enforcement of the XR-29 policy be delayed a minimum 12 months.

Reducing Access

As we have already noted, many hospitals will not have all their equipment compliant by January 1, 2016. In lieu of making the upgrades necessary to make all of the imaging department's equipment XR-29 compliant, a facility could, instead, attempt to economically triage their patients so that Medicare beneficiaries are only referred to XR-29 compliant equipment. This would require some type of up-front flagging of the patients and eliminate the need to undertake either the equipment upgrades or the administrative procedures previously outlined.

By using this approach, Medicare beneficiaries would receive treatment with the most up-to-date equipment. However, it will also likely result in reduced access to CT imaging services for Medicare beneficiaries.

As previously noted, imaging departments/facilities have a combination of compliant and non-compliant equipment. Let's assume a department with 10 CT scanners is actually a bit better than the industry average and 70% (7 scanners) are XR-29 compliant and 3 are not XR-29 compliant.

Currently, a Medicare beneficiary has access to any one of the 10 machines and can be scheduled based upon the availability of any of those scanners. Should this facility opt to keep the 3 non-compliant CT scanners in operation and only make the XR-29 compliant scanners available to the Medicare patients, then Medicare beneficiaries would experience a 30% decline in available CT scanners. In all likelihood, the would make waiting times longer or, depending upon the placement of these scanners throughout a community, make physical access to a compliant site more challenging.

Future Changes to XR-29

Finally, it should be noted that the MITA standards are constantly evolving and Section 218 of PAMA authorizes the Secretary to issue new regulations mandating that CT equipment remains

compliant with future iterations of the XR-29 standards. It is not clear how frequently or how substantive changes will need to be to warrant a revision to the XR-29 compliance standards.

Should the Secretary seek to mandate compliance with future updates to the XR-29 requirements, the Secretary provide sufficient time for the provider community to make the changes before any payment reductions might occur. As we have just outlined, the process for upgrading or improving equipment is lengthy.

We encourage imaging departments and facilities to maintain compliant equipment but we must also recognize that doing so takes time and money – something many facilities do not have an abundance of these days.

2. **Lung Cancer Screening Process**

On February 5, 2015, CMS announced a National Coverage Determination (NCD) for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT). This NCD adds LDCT to the Medicare program provided that a lung cancer screening counseling and shared decision-making visit occurs prior to the LDCT. It is important to note that this screening/shared-decision making visit must occur prior to the LDCT, for payment to be made.

AHRA is pleased to see CMS adding preventive imaging services to the Medicare benefit, however, we have several concerns and questions regarding the implementation of this new policy.

Question

Some institutions have implemented changes to their ordering system that require the ordering professional to attest that the screening counseling and shared decision-making requirements have been met. The facilities are placing this attestation into the patient's medical record as confirmation that the required services have occurred.

Should CMS conduct a post-payment review and determine that the screening and/or shared decision making requirements were NOT met by the ordering physician, would the imaging facility be subject to recoupment for the CT even though the hospital, in good faith, performed the CT believing that the required counseling had occurred?

Discussion

AHRA is pleased to see that CMS will create separate HCPCS codes for the lung cancer screening and LDCT services respectively. This separation should allow imaging departments to administer LDCT with confidence and should help avoid billing complications. AHRA encourages timely implementation of the new HCPCS codes because many imaging departments have a backlog of LDCT claims waiting to be billed.

In the NPRM, CMS states,

> "For the CY 2016 OPPS, we are proposing to assign HCPCS code GXXX1 to proposed renumbered APC 5822 (Level 2 Health and Behavior Services) (existing APC 0432) and HCPCS code GXXX2 to proposed renumbered APC 5570 (Computed Tomography without Contrast) (existing APC 0332)."

This new benefit was announced on February 5, 2015. Per CMS instructions, imaging facilities have been holding claims for LDCT services provided after February 5th. The NPRM only speaks to use of the new HCPCS codes for CY 2016.

Recommendation

CMS should revise this language to make it clear that the new HCPCS codes are to be used for claims imaging facilities have been holding since the benefit was announced.

Conclusion

Your consideration of these comments/questions is appreciated. Should you have any questions or need any additional information, please do not hesitate to contact: Sheila M. Sferrella, CRA, FAHRA, ssferrella@regentshealth.com Chair, AHRA Regulatory Affairs Committee.

Sincerely,

Edward J. Cronin, Jr., CAE
Chief Executive Officer

CT Compliance

Date Created: Thursday, July 16, 2015
Date Closed: Monday, August 17, 2015

Total Responses (# individual members): 520
Total Responses (# member facilities) : 491
Member Facility Response Rate: 29%

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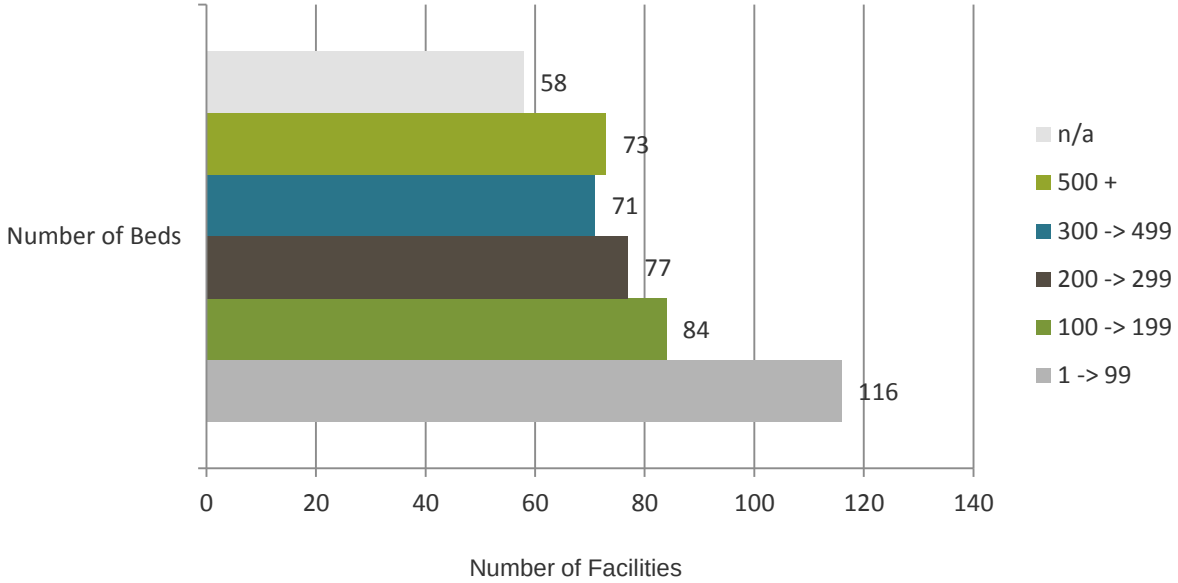
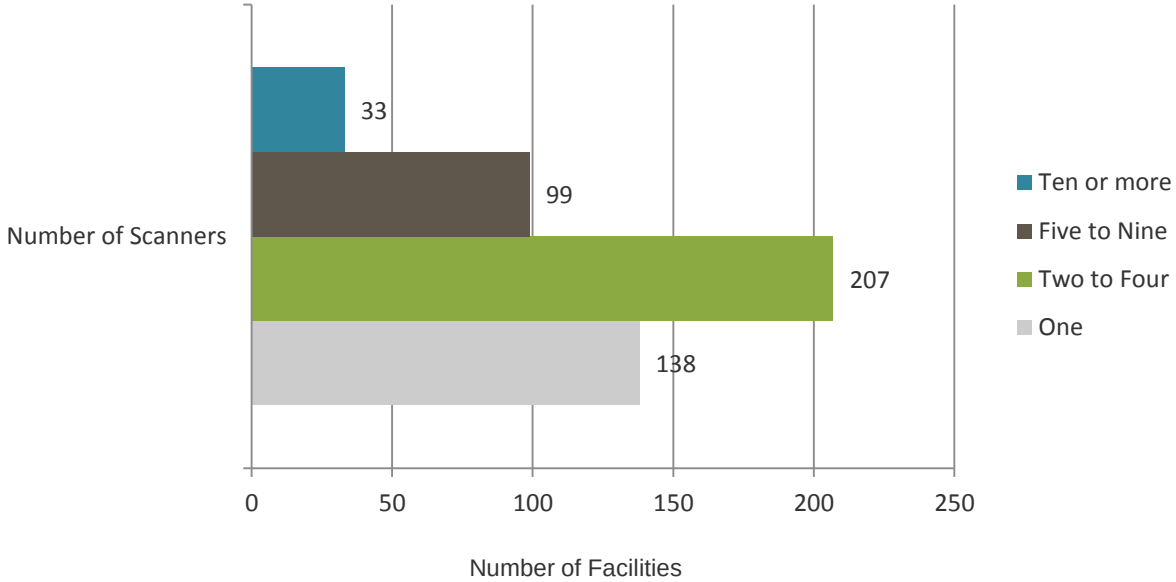
Q2: Facility Bed Size

Answered: 479



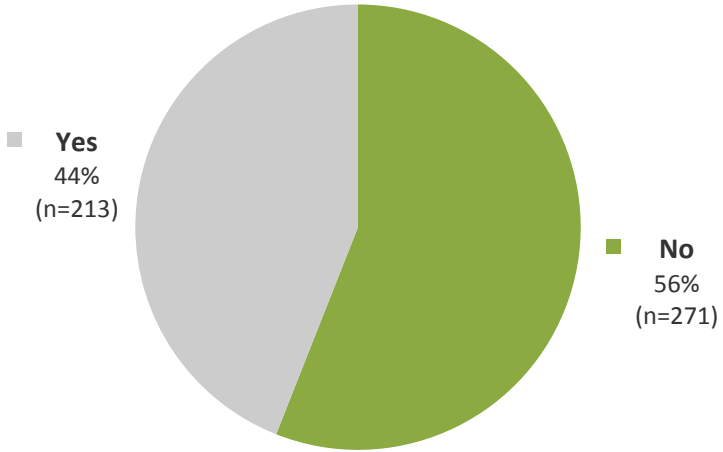
Q3: How many CT scanners does your facility/system have? If you are part of a system and/or manage multiple facilities, please provide the total number of CT scanners across all.

Answered: 477



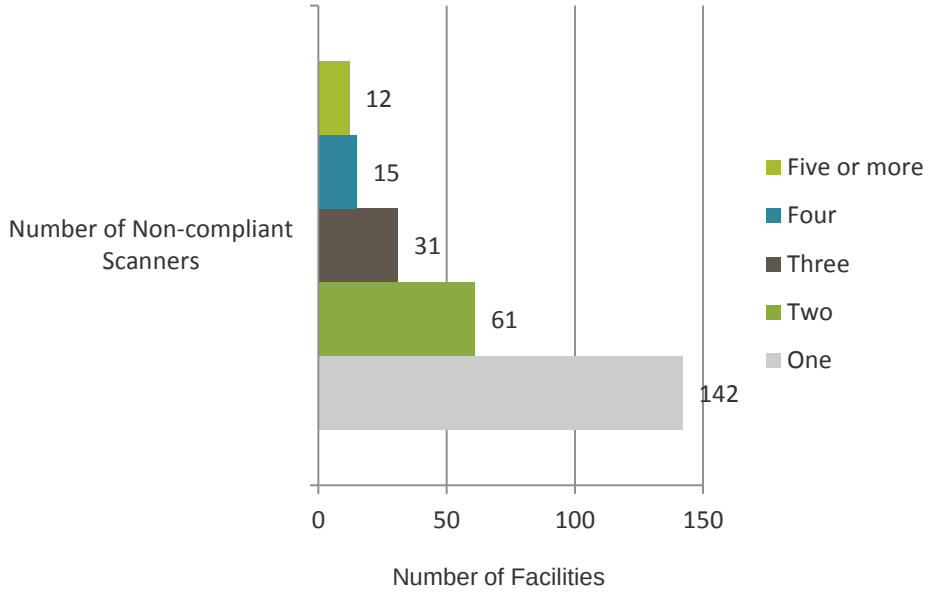
Q4: Are they all compliant for the MITA Smart Dose CT standard?

Answered: 484



Q5: If non-compliant, how many scanners are not?

Answered: 261



Q6: Will they be compliant by January 1, 2016?

Answered: 411