ahra
the association for medical imaging management

September 8, 2015

The Honorable Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1631–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 Physician Fee Schedule (MPFS) proposed rule (CMS-1631-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 the following issues:

1. NEMA Standard XR-29
2. Low-Dose CT Lung Cancer Screening billing requirements
3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services
4. Phase-in of Significant Relative Value Unit (RVU) Reductions
5. Practice Expense Inputs for Digital Imaging Services
6. Definition of Eligible Professional (EP) for Participation in PQRS
7. Equipment Maintenance

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)

490-B Boston Post Road, Suite 200 | Sudbury, MA 01776
Toll-Free: (800) 334-2472 | Phone: (978) 443-7591 | Fax: (978) 443-8046 | Email: info@ahraonline.org | Website: www.ahraonline.org

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.

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.

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.

3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act (PAMA) requires that by January 1, 2017 all ordering professionals must consult with an applicable appropriate use criteria prior to ordering certain imaging services. PAMA also requires the Secretary to specify applicable appropriate use criteria, developed or endorsed by national professional medical specialty societies or other provider-led entities, by November 15, 2015.

AHRA would like to echo the American College of Radiology (ACR) and express our support for CMS's proposed definition of a "provider-led" entities. The definition in the proposed rule will ensure that the appropriate use criteria be developed with evidence-based clinical science and not by groups such as radiology benefit managers (RBMs) that would lack the clinical consensus required by PAMA.

AHRA is concerned however, with the implementation timeline established by PAMA. We note that CMS is not including any proposals in this year's MPFS to implement the provisions establishing the January 1, 2017 deadline because "it is important that we first establish through notice and comment rulemaking the process by which applicable AUC will be specified as well as the CDS mechanisms through which ordering providers would access them."

Once CMS settles on clear definitions and establishes a process for Clinical Decision Support (CDS) mechanisms, then the industry will need at minimum 12 to 18 months to establish processes and modify systems to comply.

PAMA requires the following data elements on claims (with a few exceptions) in order for the radiologist to be paid:

1. Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the services.

2. Whether or not the service adheres to such criteria; and

3. The national provider identifier of the ordering professional.

As you might imagine, in order to communicate the data elements above, imaging departments and centers will need considerable time to update their systems and processes. Imaging workflows involve multiple departments and personnel types that will need efficient ways to record and share the necessary information. Mandates that affect these workflows must be implemented in a reasonable way that provides imaging departments the time they need to incorporate the mandate across these processes, especially when a large portion of imaging orders are submitted via a paper (vs electronic system) or faxed in.

Hospitals and imaging centers will not be able to prepare for this mandate until CMS clarifies exactly how they expect the data elements above to be communicated. If the specifics are released in the 2017 physician fee schedule and the mandate remains January 1, 2017, then it will be very difficult for the industry to be prepared.

Finally, AHRA wants CMS to understand that the CDS mandate will impose significant costs upon imaging departments. Operating budgets are typically developed a year or more ahead of time and many hospitals and imaging centers may have difficulty properly budgeting for CDS software that is yet to be developed and priced.

For these reasons, we urge CMS to clarify their expectations for the various CDS mechanisms at least one year and preferably 18 months prior to the enforcement of the CDS mandate.

4. **Phase-in of Significant Relative Value Unit (RVU) Reductions**

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a two year period. CMS outlines in this NPRM a proposed methodology for implementation of this statutory provision. AHRA disagrees with the proposal to consider the 19 percent reduction as the maximum first year reduction and to phase-in any remaining reduction greater than 19 percent in the second year of phase-in.

We believe that the proposed approach does not capture the spirit of the legislation in dampening the impact of significant payment reductions on a year to year basis. We understand CMS' concern about codes estimated to be reduced by 19 percent in a given year taking the full reduction compared to codes which meet the 20 percent threshold receiving a smaller reduction. This could lead to temporary distortions in relativity, but the larger intent of this statute is to lessen the impact on physicians on a year to year basis. A 50 percent phase-in approach for years 1 and 2 would reduce the impact of large annual reductions. For example, a code which receives a 60 percent reduction, under CMS' proposal, would be reduced 19 percent in year 1, but 41 percent in year 2.

Therefore, the AHRA strongly supports a 50 percent phase-in approach for year 1 and 2, rather than the proposed 19 percent maximum methodology.

5. **Practice Expense Inputs for Digital Imaging Services**

AHRA appreciates CMS' efforts to work with the specialty societies in ensuring appropriate practice expense inputs for digital imaging services in place of the desktop computer proxy that was implemented for CY 2015. These collaborative efforts resulted in the proposed increase in the cost of the picture archiving and communication system (PACS) from $2,501 to $5,557, which reflects the amount of the invoices provided for the "Technologists Workstation." This total does not capture the amount captured by the invoices provided for the "Rad (professional) Workstation."

While including the actual cost of the "Technologist Workstation" is a positive update, AHRA believes the professional workstation is also an important component of a PACS system such that both the technologist and professional workstations should be considered direct expenses within the practice expense (PE) Methodology.

CMS is seeking comment on whether including the professional workstation as a direct PE input for applicable codes would be appropriate, given that the resulting PE relative value units (RVUs) would be assigned to the global and technical components of the codes.

The professional workstation is a direct expense for the following reasons:

1. The station is used for individual studies "one at a time "in the office (non-facility) setting;

2. The use of this station involves a bi-directional exchange between technologist and radiologist frequently while the patient is still on the table and the TC is being provided;

3. For the subsequent interpretation, the professional workstation is often provided in the same physical office space and typically provided by the same practice. Therefore, the provider providing the technical component and the interpreting physician share the same Tax Identification Number; and

4. Considering the professional workstation a direct expense follows the precedent established by the prior film-based inputs and subsequently replaced by the digital inputs. Supply items such as alternators and film are analogous to a professional workstation and necessary for the service performed.

Codes for mammography services are currently being reviewed by the AMA Current Procedural Terminology® (CPT) Editorial Panel and the Relative Value Scale Update Committee (RUC). Mammography requires a considerably higher priced professional workstation as the resolution of the monitors must be higher to satisfy the Mammography Quality Standards Act (MQSA) requirements. It is our understanding that the ACR provided representative invoices to the AMA for this mammography physicians' workstation.

AHRA encourages CMS to recognize these higher priced direct inputs as RUC recommendations for mammography are shared with CMS.

CMS is also seeking comment on whether or not the PACS workstation used in other imaging codes is the same workstation that is used in the post-processing described by CPT code 76377 *(3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation),* or if a more specific workstation should be incorporated in to the direct PE input database. The CPT descriptor for 76377 indicates that 76377 requires "image post-processing on an independent workstation." This independent workstation requires a separate computer from the PACS system. Previously, this equipment supply item was represented by CMS supply code ED014 (computer workstation, 3D reconstruction CT-MR) to which 38 minutes of equipment time had previously

been assigned. ED014 is no longer in the CMS PE Database. AHRA recommends that this item be restored and the appropriate clinical staff time be assigned to it. The PACS equipment direct input should also be maintained for 76377 to enable necessary digital archiving and storage activities. **In summary, AHRA recommends that 76377 maintain 38 minutes of equipment time for restored supply item ED014 and 76377 also maintain a separate PACS related direct input.**

6. **Definition of Eligible Professional (EP) for Participation in PQRS**

In 2015, CMS' timing and handling of the determination that EPs practicing in Independent Diagnostic Testing Facilities (IDTFs) would not be able to participate in PQRS was confusing and unclear. Announcing that IDTFs must participate in PQRS (when those EPs have not participated since program inception) almost four months into the reporting year caused much confusion and alarm for EPs practicing in that setting. The reverse determination several months later added to the confusion. **While the AHRA appreciates CMS clarification of EP for purposes of participating in the PQRS, we ask that CMS stay consistent in applying PQRS eligibility to EPs practicing in IDTFs.**

7. **Equipment Maintenance**

AHRA appreciates CMS' openness to new data on equipment maintenance costs and we welcome the opportunity to work with the agency to ensure that maintenance costs are represented appropriately in the MPFS.

CMS' calculation of practice expense relative value units (PERVUs) includes a formula for determining the cost of equipment on a per minute basis. One of the variables in the agency's equipment cost formula is maintenance as a percentage of the purchase price of the equipment. Currently, this percentage is 5 percent (0.05) for all medical equipment regardless if it is a piece of furniture or an MRI.

AHRA points to a 2014 survey of the Radiology Business Management Association (RBMA) members which found that the maintenance cost percentage for imaging equipment exceeds CMS' current assumption of equipment maintenance costs (5 percent). For all imaging modalities, the equipment maintenance factor was 10 percent of the purchase price except for mammography, where it was 15 percent. Moreover, these results were consistent with actual maintenance contracts that are offered by original equipment manufacturers (OEM) or third-party (aftermarket) contractors. On average, maintenance agreements average between 7 to 12 percent of an equipment's purchase price. Maintenance contracts for mammographic equipment tend to **be higher due** to: (1) the frequent need to replace digital detectors (approximately every 15 months) at a cost of $50,000 to $60,000 and (2) the additional quality control/quality assurance requirements required for mammography. A copy of a typical mammography maintenance contract was provided in the comments referenced submitted from RBMA.

Maintenance Factor is Variable

In the CY 2016 proposed rule (page 41695), CMS states, "…it is clear that the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment." AHRA agrees with CMS and the results of a 2014 RBMA member survey support this. The agency goes onto say, "…that most of the information for maintenance costs we have received is for capital equipment…" AHRA concurs. Capital equipment includes expensive advanced technology, like MRI and CT, which are more expensive to maintain.

CMS' use of variable interest rates based on equipment cost and useful life could be a model for maintenance costs. In the CY 2013 final rule, CMS updated the interest rates used in calculating equipment costs based on those from the Small Business Administration (SBA).

Table 3 – SBA Maximum Interest Rates (page 41695)

Price	Useful Life	Interest rate (%)
<$25K	< 7 years	7.50
$25K to $50K	< 7 years	6.50
>$50K	< 7 years	5.50
<$25K	7+ years	8.00
$25K to $50K	7+ years	7.00
>$50K	7+ years	6.00

We suspect, as the RBMA survey and other commenters suggest, that equipment cost is a more accurate indicator of equipment maintenance than useful life (e.g., an exam table has a useful life of 15 years vs. five years for a MRI). CMS could apply the same rationale to maintenance cost factors with multiple rates depending on the price/cost of the equipment.

Publically Available Data

In the proposed rule, CMS continues to "seek a source of publicly available data on maintenance costs for medical equipment to improve the accuracy of the equipment costs used in developing the PE RVUs." While laudable, we are unaware of any such public dataset. The agency also is leery that "…very small numbers of invoices are likely to reflect typical costs…" while acknowledging that invoices are difficult to obtain. AHRA would appreciate further guidance from CMS on the type and quantity of information it seeks.

Conclusion

ahra
the association for medical imaging management

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

490-B Boston Post Road, Suite 200 | Sudbury, MA 01776
Toll-Free: (800) 334-2472 | Phone: (978) 443-7591 | Fax: (978) 443-8046 | Email: info@ahraonline.org | Website: www.ahraonline.org

CT Compliance

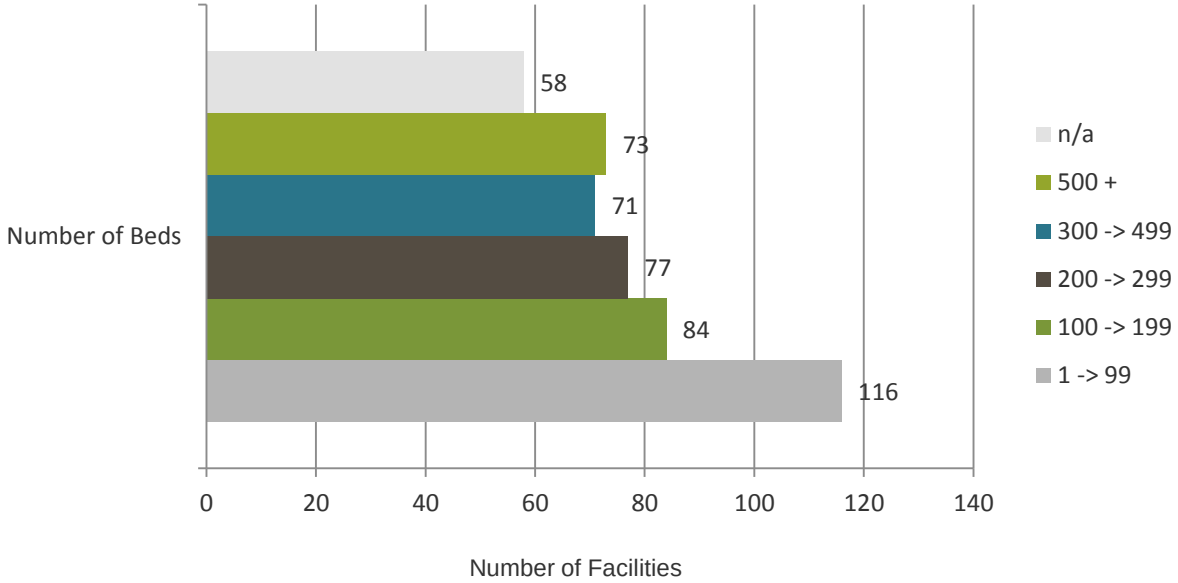
Date Created: Thursday, July 16, 2015
Date Closed: Monday, August 17, 2015

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

ahra
the association for medical imaging management

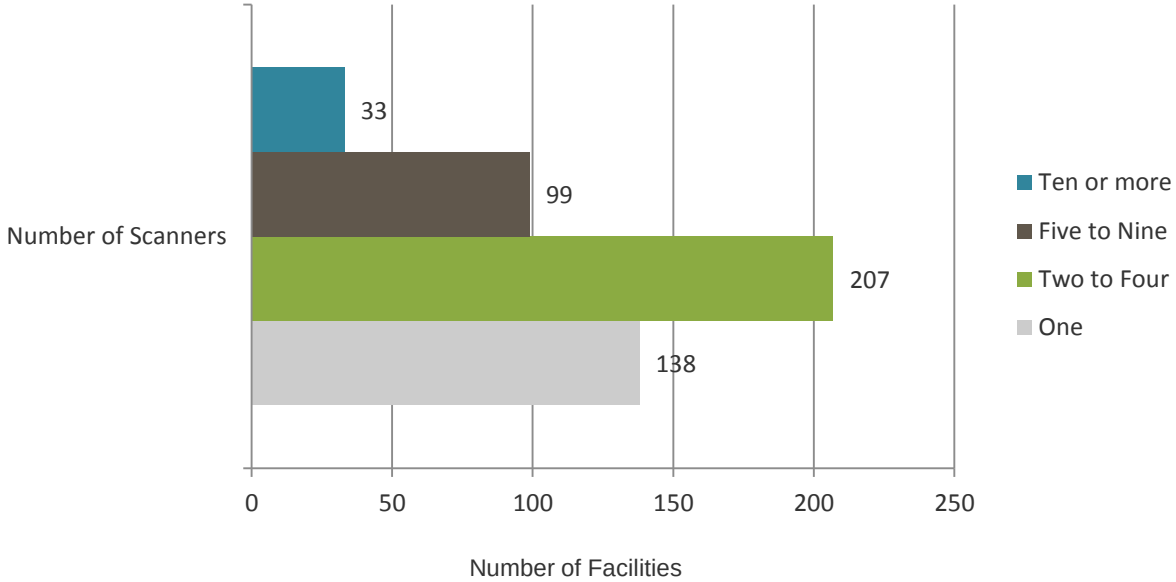
Q2: Facility Bed Size

Answered: 479



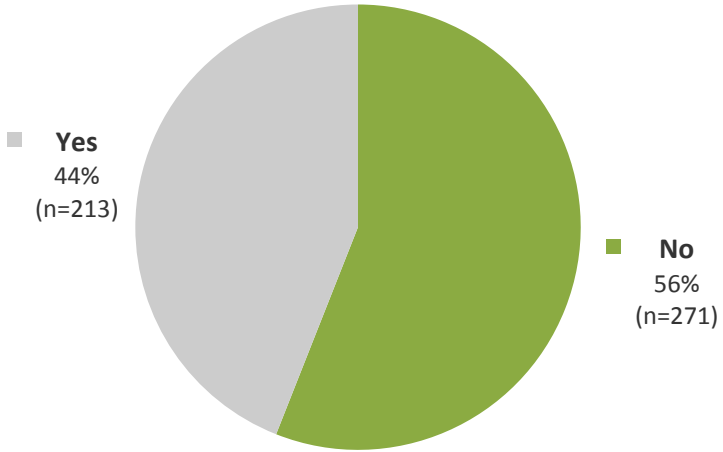
Q3: How many CT scanners does your facility/system have? If you are part of a system and/or manage multiple facilities, please provide the total number of CT scanners across all.

Answered: 477



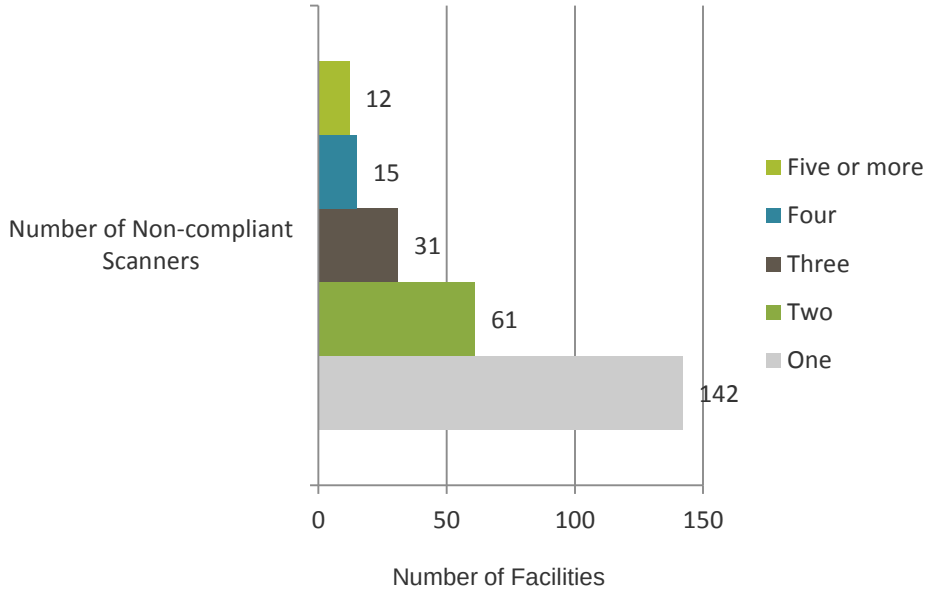
Q4: Are they all compliant for the MITA Smart Dose CT standard?

Answered: 484



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

Answered: 261



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

Answered: 411