



June 12, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1677-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices

Dear Administrator Verma:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the Inpatient Prospective Payment System (IPPS). The ACR provides comment on the following important issues:

- 1) National cost center cost-to-charge ratios (CCRs) for radiology, CT scan, and MR.
- 2) Proposed changes to imaging accreditation (42 CFR 414.68) requiring Accrediting Organizations (AOs) to post final survey results and acceptable plans of corrections on their websites.
- 3) Request for information (RFI) on ways to reduce burdens on providers and patients.

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National cost center CCRs for radiology, CT scan, and MRI.

In the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS) final rule, CMS adopted a policy to calculate the CCRs for the CT and MR cost centers that did not include those hospitals that used the “square foot” allocation methodology for reporting costs. CMS indicated that it was adopting this policy for four years in order to provide hospitals with time “to transition to a more accurate cost allocation method and for the related data to be available for rate setting purposes.”¹ CMS has not adopted the same policy for the IPPS as the OPPS and includes all hospital cost reports to determine MR and CT CCRs irrespective of the cost allocation methodology used by the hospital.²

ACR has two requests related to this issue:

1. In the FY 2018 IPPS final rule, ACR requests that CMS set weights based on a single diagnostic radiology CCR—the same policy that CMS applied before it created separate CT and MR standard cost centers; and
2. In the CY 2018 OPPS rule, CMS not move forward with the policy it finalized in CY 2013 to use all hospital cost reports including those hospitals that allocate CT and MR costs using the square foot methodology and that it follow the same policy ACR is suggesting for the FY 2018 IPPS.

ACR makes this request because of evidence that the CCRs for CT and MR are incorrect and are causing payments for hospitals patients in need of CT and MR services to be too low.

ACR recognizes that CMS’ policy for CT and MR CCR has been in place for several years and CMS did not include a specific proposal in the IPPS related to this issue. As such, CMS may view ACR’s request as out-of-scope. However, ACR believes the FY 2018 IPPS rule, by not following the same policy as the OPPS, illustrates the problem that ACR would like to avoid exacerbating in the CY 2018 OPPS where the impact is more significant.

Rationale for Separate Hospital Reporting of CT and MR Cost Centers

CMS’ policy on this issue was raised in the FY 2009 IPPS rule where it discussed “a contract [awarded] to RTI to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across

¹ Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Final Rule, December 10, 2013, page 74847.

² Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care; Hospital Prospective Payment System and Fiscal Year 2014 Rates, Final Rule, August 19, 2013, page, 50523.

services within cost centers.”³ Charge compression describes higher percentage mark-ups on low cost items than high cost items. Using a single CCR that groups low and high cost items will result in underpayment of the high cost item and overpayment of the low-cost item. While RTI’s study was largely undertaken because of concerns about high cost medical devices being reported in the same cost center as low-cost supplies, RTI’s analysis went beyond that narrow issue.

For MR and CT, the charge-compression hypothesis would set out to determine if higher cost diagnostic tests like MR and CT have lower percentage mark-ups than lower cost X-ray tests. While MRI and CT scans are more expensive than traditional X-rays, the results of creating separate cost centers for them has produced the opposite result than would be expected—higher mark-ups for the more expensive services than the less expensive services. As this result is the opposite of the hypothesis, the hypothesis is unproven. However, it does not mean that the opposite is true—that MR and CT have lower percentage mark-ups than other diagnostic X-ray tests. As the results are counter-intuitive, it makes more sense to conclude that how costs are reported to these cost centers is problematic than it does to conclude that CT and MR are overvalued with a single radiology CCR.

Indeed, public comments acknowledged by CMS on this issue suggest the data is problematic:

The commenters believed that the CCRs for advanced imaging may reflect a misallocation of capital costs on the cost report. They further stated that this could indicate that many hospitals are reporting CT and MRI machines as fixed equipment and allocate the related capital costs as part of the facility’s Building and Fixtures overhead cost center instead of reporting the capital costs directly in the Radiology cost center.⁴

In responding to commenters’ statements that hospitals would have problems with accurate creation of these new standard cost centers, CMS acknowledged that the allocation of very high cost “moveable equipment” to the department using that equipment, may not be a standard practice in hospitals. CMS recognized that such practice would not produce accurate CCRs and, it is for this reason that CMS delayed use of some hospital CCRs used to set OPSS rates until CY 2018.

Policy Impact of Separating CT and MR Cost Centers

Figure 1 below illustrates the trajectory of selected single procedure OPSS rates for advanced and non-advanced imaging procedures. This example is being used because single IPSS rates cannot be identified. The rate in CY 2017 under the OPSS for CT

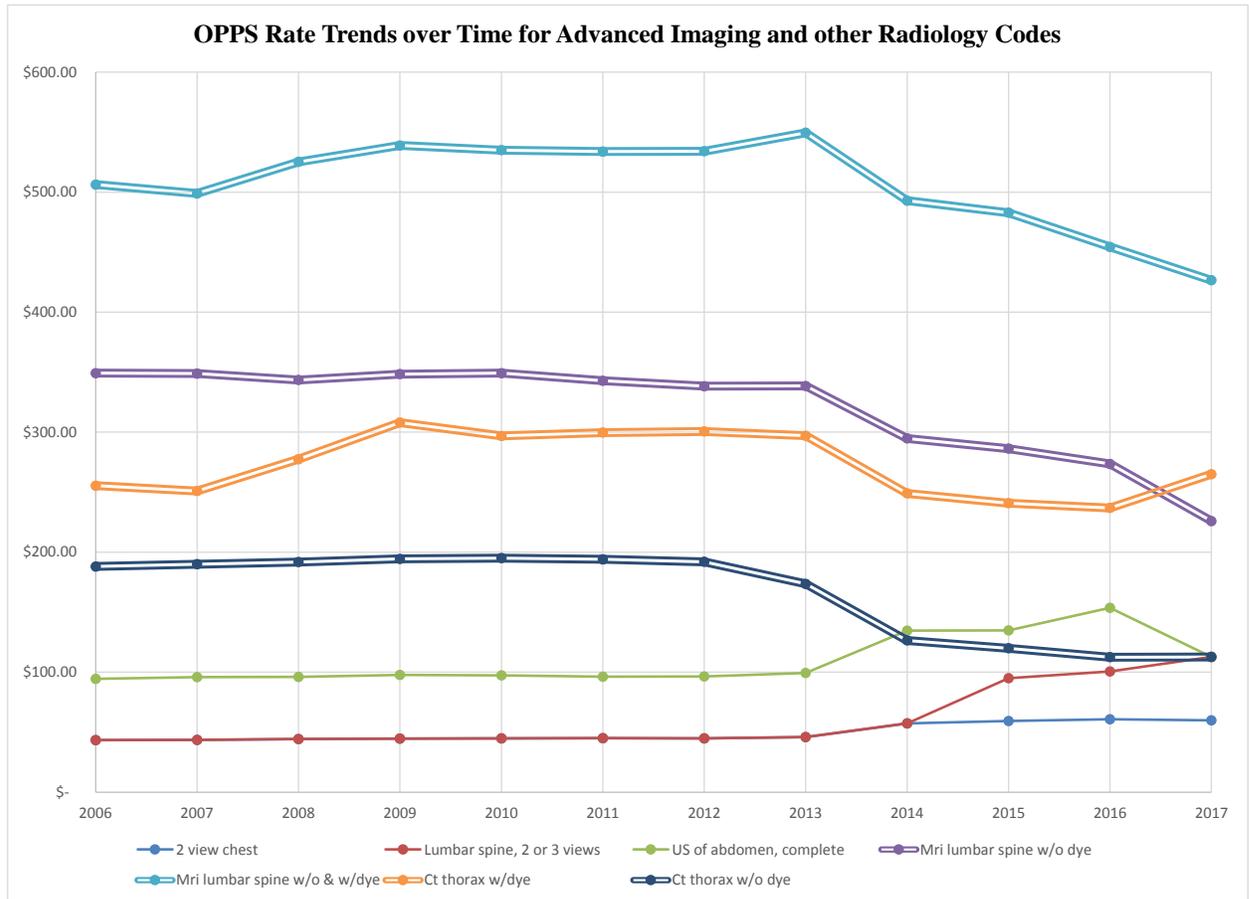
³ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, Final Rule, August 19, 2008, page 48451.

⁴ FY 2009 IPSS Final Rule, page 48456.



thorax w/o dye is now the same as that for an ultrasound of the abdomen complete and for an X-ray of the lumbar spine 2-3 views. These are all high-volume procedures, and advanced and non-advanced imaging are being paid at the same levels. Other high volume advanced imaging procedures have rates moving in the same direction. This pattern of payment does not fit the hypothesis of “aggregation bias” described by RTI based on 2007 data.

Figure 1. Trends in Rates for Selected Imaging Procedures: Advanced and Non-Advanced



The Problem is Getting Worse, Not Better

In an Excel Workbook accompanying this letter and illustrated in the chart below, we show the hospital level billing practices for selected CT and MR claims. These data show that only about half of all hospitals paid under the OPSS had CT and/or MR cost centers that were reporting CCRs using the preferred methods (“dollar value” or “direct assignment”). Hence current rates have declined based on using partial data. When all data are used for the CY 2018 (like is occurring now for the IPPS), it is unlikely that more hospitals will have changed their cost reporting to the method preferred by CMS.



These data show that hospitals have either been unable or unwilling to make the changes CMS regulations mandated.

HCPCS	Short Descriptor	Total Number of Hospitals	Number of Hospitals with MR or CT Cost Centers	Percent of Hospitals with MR or CT Cost Centers	Number of Hospitals with MR/CT Cost Centers Using Non-Square Footage Allocation Method	Percent of Hospitals with MR/CT Cost Center using Non-Square Foot Allocation Method	Geomean Cost of Total Hospitals	Geomean Cost of Hospitals with MR/CT Cost Centers Using Non-Square Footage Allocation Method	Percent Difference Between All Hospitals and Hospital Correctly Complying with CMS MR/CT Cost Center Billing
70553	Mri brain stem w/o & w/dye	2,926	2,020	69.0%	1,467	50.1%	\$ 360.51	\$ 335.76	-7.4%
71250	Ct thorax w/o dye	3,187	2,145	67.3%	1,541	48.4%	\$ 97.89	\$ 80.86	-21.1%
71260	Ct thorax w/dye	3,074	2,114	68.8%	1,519	49.4%	\$ 125.59	\$ 100.39	-25.1%
72148	Mri lumbar spine w/o dye	2,975	2,039	68.5%	1,472	49.5%	\$ 254.28	\$ 231.25	-10.0%

Notes

MRI Agents included in the analysis: A9575, A9576, A9577, A9578, A9579, A9581, A9583, A9585

CT Agents included in the analysis: Q9951, Q9953, Q9956, Q9957, Q9958, Q9961, Q9962, Q9963, Q9964, Q9965, Q9966, Q9967

Other allocation methods include dollar allocation and direct allocation.

The IPPS rule shows the CCRs that will be in use under the OPSS if CMS uses all CCRs for the CT and MR cost centers irrespective of the cost allocation method that the hospital is using. As noted above, CT Scans have a CCR of 0.037 and MRI is 0.077.⁵ A CCR of 0.037 suggests that hospitals are charging 27 times their costs for a CT exam. It is unreasonable to assume that this is correct. Further, ACR notes that this problem has become worse, not better since 2009. In the FY 2009 IPPS rule, CMS reported a CCR for CT of 0.054 which is higher than the CCR of 0.037 reported in the FY 2018 IPPS proposed rule.⁶

When CMS mandated that hospitals create a separate cost center for implantable devices to solve the aggregation bias problem, hospitals were able to comply and the vast majority successfully implemented a cost center aligned with revenue code 0278 in a relatively short time. Billing practices for expensive implantable devices show a high rate of compliance with this CMS mandate, and it appears to have helped address the aggregation bias problem for high cost implantable devices. This responsiveness of hospitals shows that the creation of a cost center in cost reporting that does not reach into the depreciation and amortization schedules that require major accounting system changes for high cost moveable equipment can be accomplished in a relatively short time. Devices are expensed each year, and do not involve separate schedules that are updated annually and allocated across departments. The assignment of a single revenue code and its link to a hospital department was a relatively straightforward change to hospital accounting and aligned cost reporting.

⁵ Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates, Proposed Rule, April 28, 2017, page 19868.

⁶ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, Final Rule, August 19, 2008, page 48456.



The change required to create standard cost centers for CT and MR was much more complex and hospitals were unable to be responsive. The CCRs that appear in the accompanying Excel Workbook for selected CT and MR procedures also show a significant number of CCRs that are close to zero. These near zero CCRs indicate that even when hospitals create standard cost centers, they are likely not able to accurately re-allocate many costs that are already allocated across hospital departments to new CT and MR departmental cost centers. For these hospitals, the CCRs probably reflect allocations of staffing and dedicated departmental expenses, while the costs of equipment, some costs associated with space (e.g., lead in walls), other administrative costs have been spread across all hospital departments and have not been moved. The presence of these near zero CCRs will contribute to under-estimate costs used in rate setting, pulling rates for CT and MR procedures down below their actual cost in rate setting and further eroding payment accuracy. No other high cost technologies are treated in this manner.

Hospitals have standard accounting practices for high cost moveable equipment and it is inconsistent and burdensome to expect them to account for these two types of equipment in a different manner than they deal with other types of equipment. As CMS moves away from granular procedure specific payment mechanisms across payment systems, it is inconsistent to focus on these two technologies treating them differently from all other technologies.

The ACR's concerns are farther reaching given the linkage of this policy in IPPS to the OPSS. The use of separate CT and MR CCRs created unintended consequences on the technical component of these codes in the Physician Fee Schedule (PFS). If this policy is finalized and fully implemented, the resulting reductions in hospital payments would also affect the office practice setting. This is because the OPSS technical payments would fall below the payment rates in the PFS causing further cuts as mandated by the Deficit Reduction Act of 2005 (DRA). The DRA mandates that the PFS technical payments be paid at the PFS rate or HOPPS rate, whichever is the lower. The ACR believes that these linked policies heighten the importance of ensuring that any changes made to the IPPS and thus the OPSS methodology are fully justified. The ACR is an advocate for payment stability in both the hospital and office settings where radiologists primarily work.

Don't Continue with the Planned Policy

Proceeding with implementation of the current IPPS rule policy in the OPSS in CY 2018 rule making will further depress CT and MR rates resulting in inappropriately low rates and cost for many advanced imaging procedures. ***ACR recommends that in the OPSS and the IPPS, CMS set weights based on a single CCR -- the diagnostic radiology CCR—the same policy that CMS applied before it create separate CT and MR standard cost centers.***



Proposed Changes Related to Survey and Certification Requirements – Posting of Survey Reports and Acceptable Plans of Correction (PoCs)

As a CMS-approved Accrediting Organization (AO) for Advanced Diagnostic Imaging (ADI), ACR was both surprised and deeply concerned by the proposal to require ADI AOs to agree to post accredited facilities' survey reports and acceptable plans of correction on the AO's website. Our surprise stems from the fact that **hospitals are exempt from Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which requires suppliers of the technical component of advanced diagnostic imaging (ADI) services to be accredited by a designated accrediting organization in order to receive Medicare reimbursement.** For this reason, we would not have anticipated that such a proposal would be included in the *hospital* inpatient payment rule and we fear that other stakeholders who should have been afforded the opportunity to comment upon this weighty issue have not received fair notice. We believe it likely, that by including this proposal in an 1837-page fast-tracked hospital inpatient rule, CMS will not have the benefit of input from a large contingent of affected stakeholders including non-hospital-based ADI suppliers and other experts in health care quality and safety.

Likewise, we find it disconcerting that although the NPRM includes several paragraphs describing the background and CMS' rationale for requiring AOs with deemed status to publically post survey results, the inclusion of ADI suppliers/AOs in this proposed policy appears to be an afterthought with no meaningful consideration given to ADI-specific implementation issues. For example, the discussion about AO versus State Survey Agency disparity rates based on deficiency findings is not at all relevant with respect to ADI accreditation because State Survey Agencies do not evaluate ADI services. Moreover, because State Survey Agencies do not evaluate ADI services, ADI AOs do not have "survey processes that are comparable to those survey methods, procedures, and forms required by CMS for conducting federal surveys for the same health care facility type". Because the processes and terminology used by ADI AOs is unique, it is not even clear what CMS means by "final accreditation reports" in the context of ADI AOs. Indeed, there is such significant variability in the standards, methods, processes and forms used by the four ADI AOs⁷, we believe that comparison of imaging facilities based on survey reports and POCs would be not only meaningless and confusing, but also potentially misleading. Certainly, meaningful comparison of survey reports across ADI AOs would not be possible because the four ADI AOs utilize substantially different criteria in evaluating facility performance, and those criteria are not necessarily even referenced in the final reports that CMS is proposing be posted. An ADI supplier that meets one ADI AO's program requirements does not necessarily provide better imaging quality than one that initially fails to meet another ADI AO's more stringent requirements.

⁷ See GAO, *Medicare Imaging Accreditation: Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services*, [GAO-13-246](#) (Washington, D.C.: May 31, 2013).



Even comparison of facilities accredited by the same AO can likewise be misleading in that some criteria evaluated are fundamentally more meaningful indicators of quality and safety than other criteria. As an example, a facility that is initially denied accreditation because it inadvertently failed to submit all required images with its application doesn't necessarily raise the same quality and safety concerns as a facility denied accreditation for failure to properly maintain radiologic equipment or for failure to produce diagnostic quality images; posting of survey reports will not provide consumers with sufficient information to distinguish between such facilities. Finally, consumers could be confused and/or draw incorrect conclusions in attempting to compare non-hospital based imaging facilities for which survey reports/POCs would be posted and hospital based facilities for which they would not. In short, the proposed policy would fail to serve its intended purpose of providing meaningful data to consumers permitting them to make informed decision in choosing health care providers.

Also, due to the nature of the advanced imaging modalities evaluated, ACR accreditation reports are medically detailed and technologically complex. This is essential to provide sufficient and relevant feedback to facilities so that they may improve the quality of imaging and their patients' care. In our experience, making such information publicly available to lay audiences introduces misinterpretations and confusion. Additionally, PoCs may contain names of facility personnel and sensitive personnel-related information that could be damaging to an individual's reputation or career; publishing such information could also create liability for facilities and AOs.

Of even greater concern, however, is the likelihood that the proposal would undermine the fundamental objective of accreditation and contravene Congress' intent to utilize accreditation to improve the quality and safety of Medicare-funded healthcare services. Accreditation in the health care setting existed on a voluntary basis long before it was used to demonstrate compliance with CMS requirements. In fact, ACR's long-held commitment to improving quality and safety in medical imaging through the provision of accreditation services dates back to 1963. Fundamentally, the purpose of accreditation in the healthcare setting is to promote quality improvement and enhanced safety practices. ACR's ADI accreditation program utilizes peer review to assess facilities' adherence to publically available program requirements that are developed by physicians and medical physicists, with expertise in the specific imaging modality being evaluated. The accreditation process relies upon honest and open communication to identify any areas requiring improvement, so that facilities can make any changes required to bring them into compliance with program requirements. The process is not meant to be punitive, but rather educative and transformative. However, absent assurances that any shortcomings identified as part of the quality improvement process will be kept private from those that might use the information to the detriment of the facility, communication between the facility and the AO will likely be more guarded if this CMS proposal is adopted.



Followed to its logical conclusion, facilities for whom accreditation is optional may choose to forego accreditation altogether and those that must be accredited will be incentivized to opt for the least rigorous accreditation program rather than one most likely to improve imaging quality.

Congress and state legislatures have recognized the importance of confidentiality in healthcare quality improvement activities and have repeatedly sought to protect the integrity of such activities by protecting the confidentiality of the process. Section 1865(b) of the Act clearly demonstrates Congress' intent in this regard by explicitly prohibiting the Secretary from disclosing accreditation surveys (except for home health agencies) "except to the extent such survey and [related] information relate to an enforcement action taken by the Secretary." Likewise, to encourage the reporting and analysis of medical errors, the Patient Safety and Quality Improvement Act of 2005 provided a safe harbor protecting "patient safety work product" and provided for significant civil monetary penalties for wrongful disclosure of information. Various states (including Illinois, Maryland and Virginia where all current ADI AOs are incorporated) afford privilege for health care peer review activities. Virginia code 8.01-581.17 (Privileged Communications of Certain Committees and Entities), to which ACR is subject, explicitly provides, "...accreditation and peer review records of the American College of Radiology and the Medical Society of Virginia are considered privileged communications."

To be clear, ACR's opposition to CMS' proposal to require posting of accreditation information should NOT be construed as opposition to providing patients with information that allows them to make better informed decisions in selecting their health care providers. To the contrary, we recognize that one of the values of accreditation (voluntary or otherwise) is in allowing a facility to demonstrate its compliance with an AO's standards. For this reason, ACR already makes our accreditation program requirements publically available on our website so a consumer can review the requirements that a facility accredited by ACR has met. We also publically post, on our website, the names of the facilities currently accredited by ACR – in other words, those facilities that have met ACR's program requirements. Consumers accessing such information from our website summary, (and from the sites of other ADI AOs who publish similar information) have far more useful information available to them than the CMS proposal would afford. Moreover, AOs' publication of their program requirements and the accredited facilities who meet those program requirements does not undermine the effectiveness of the accreditation process as CMS' proposal would, nor does it contravene the intent of Congress and state legislatures. Should CMS decide to move forward with some form of its public posting of accreditation information, we would urge that the scope of the information required to be posted be limited to the AOs program requirements and the names of facilities accredited by the AO.



In addition to the more general comments above, we would ask CMS to consider the following more specific concerns.

- Because the ADI AO proposal is included in a proposed rule for hospitals, it might be inferred that AOs would also be required to agree to post survey reports of hospitals that *voluntarily* undergo imaging accreditation even though they are not required to be accredited in imaging for purposes of CMS payment. It is our understanding that this is not CMS' intent, however we do not believe the proposed rule is at all clear in this regard. Accordingly, if CMS decides to move forward with this proposal, we ask that it include a clear statement that the policy does not apply to hospitals voluntarily participating in imaging accreditation. Without such clarifications, hospitals may decide that voluntary imaging accreditation creates too much unnecessary risk and liability and forego such accreditation altogether.
- Because CMS' proposal would require AOs to contractually agree to post specified accreditation information rather than requiring it as a matter of law (pre-emptive of conflicting state law), AOs could find themselves in a catch-22 situation. AOs cannot unilaterally waive legal privileges afforded to facilities under state law. Working through the legal and administrative challenges of such a scenario could prove daunting and expensive. Should CMS decide to move forward with its proposal, we would ask that it does so in a way that would minimize such challenges and provide ample time for AOs to assess and resolve such challenges.
- ACR does not believe CMS has provided enough detail in the proposed policy to allow us to assess the fiscal impact the policy would have on us if it were adopted. As noted above, there is significant variability in the standards, methods, processes and forms used by the four ADI AOs; we can only guess at CMS' intent as to which of ACR's template forms CMS might consider to be "final accreditation survey reports". Assuming ACR is required to adopt extensive software system changes to meet the proposed requirement, we would anticipate significant software programmer costs and a 6-9 month time frame for software development with an additional three months required for testing and staff training. Depending on CMS' expectations, we may require additional staff to redact any reports that contain names and sensitive information about facility personnel or HIPAA-protected PHI. We would also need to reassess our insurance coverage requirements to account for any additional liability associated with our compliance with the proposal. Depending on the extent to which consumers actually access the information, and contact the ACR with related questions, additional FTE may be required to field questions from consumers and accredited facilities. Also, as mentioned above, we would anticipate substantial legal outlays in navigating how best to achieve compliance with the CMS policy without violating applicable state law.



In summary, **ACR urges against adoption of the proposed policy to require ADI AOs that apply or reapply for CMS approval of its Medicare advanced diagnostic imaging program to agree to make all final accreditation survey reports as well as acceptable PoCs publically available on their website.** We believe that publication of accreditation program requirements and the names of facilities that are accredited by the AO (and thus have been found to meet the AOs program requirements) would better serve CMS' goal of transparency without undermining the effectiveness of the accreditation process.

Request for Information (RFI) on Ways to Reduce Burdens on Providers and Patients.

Clinicians and federal policymakers both agree on the need for policies to ensure the appropriate use of imaging studies. There is a statutory mandate within the Protecting Access for Medicare Act (PAMA) of 2014 for a utilization program incorporating Appropriate Use Criteria (AUC) and clinical decision support (CDS). Any known alternative to an AUC-CDS system, such as prior authorization programs, would prove burdensome to ordering physicians, deny their patients expedient decisions as to whether a study should be performed and add layers of paperwork and administrative hassle to the providers of these services.

Past Presidential budgets touted proposals to implement burdensome prior authorization programs administered by for-profit radiology benefit managers (RBMs) as a way to control advanced imaging. While almost universally opposed by all physicians due to the lack of transparency in the decision making process and the need to hire additional staff just to manage the cumbersome review process, the Congress wisely chose to pursue an alternative utilization management policy by mandating the Medicare program to use physician developed AUC. During the legislative debate, no physician groups opposed this Congressional effort supported by Democrats and Republicans in both the House and Senate.

Clinical decision support (CDS) software mechanisms which house transparent, evidence-based imaging AUC that either are embedded in commercial electronic health record (EHR) systems or accessed via a statutorily mandated free web-based portal have been promoted by the Institute of Medicine, the Choosing Wisely initiative and organized medicine as a tool to assist ordering physicians to use healthcare resources more effectively. Addendum A includes a detailed overview of CDS versus RBMs and provides rationale why CDS is the much less burdensome option.



Conclusion

Thank you for the opportunity to comment on the IPPS Proposed Rule. The above issues are of vital importance to the radiology community. If you have any questions about our comments please feel free to contact Pam Kassing at 800-227-5463 ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "William T. Thorwarth, Jr.", with a stylized flourish at the end.

William T. Thorwarth, Jr., MD, FACR
Chief Executive Office

cc: Monda Shaver, CMS
Patricia Chmielewski, CMS
Grace Im, CMS
James Poyer, CMS
Kellie Shannon, CMS
Zeke Silva, MD, ACR
Pam Kassing, ACR
Dominick Parris, ACR



Addendum A:

Clinical Decision Support v Radiology Benefits Managers

What is the Protecting Access to Medicare Act (PAMA) and why is it good for patients?

April 1, 2014, the President signed into law the Protecting Access to Medicare Act (PAMA) <https://www.gpo.gov/fdsys/pkg/PLAW-113publ93/html/PLAW-113publ93.htm>

- (A) The Secretary shall establish a program to promote the use of appropriate use criteria for applicable imaging services furnished in an applicable setting by ordering professionals and furnishing professionals

- (B) Appropriate use criteria defined.--In this subsection, the term 'appropriate use criteria' means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

This means that CMS will no longer allow the indiscriminate use of medical imaging - with its associated costs, radiation exposure, and other medical risks - in Medicare patients. Instead, CMS will take steps to bring key information to the point of care that encourages the responsible, evidence-based use of medical imaging, a rational approach also referred to as "appropriate imaging" and is meant to ensure that only patients who benefit from scans get them.

What kinds of imaging guidelines will CMS use for PAMA implementation?

In the 2015 Preliminary & Final Medicare Physician Fee Schedule (MPFS), CMS specifically referenced the American College of Radiology (ACR) and the American Academy of Family Physicians (AAFP) as examples of provider led entities which develop appropriate use criteria. Guidelines from these entities have for many years been accepted by both providers and payers as the "standard of care" for determine when to scan a patient. These same guidelines for the basis for all commercial Utilization Management programs in use today.

What kinds of mechanisms will be used to ensure compliance with imaging guidelines?



Most in the healthcare industry believe and hope that the PAMA implementation will be accomplished by leveraging provider-side assets to deliver guidelines through integrated Clinical Decision Support (CDS), rather than by having Radiology Benefit Managers (RBMs) deliver the same “outside in” red tape solution that is known to cause frustration and delays in privately insured populations. The following sections describe key differences between the CDS and RBM.

What are RBMs and why are they a bad idea for patients?

RBMs are an outsourced function of insurance companies that work by inserting red tape and additional third parties between patients and the care they need.

Yet despite their aggressive tactics, RBMs are usually ineffective at actually controlling costs. For example in 2013 the Congressional Budget Office (CBO) conducted a study stating that RBMs would not reliably produce any savings for Medicare Patients:

http://www.cbo.gov/sites/default/files/cbofiles/attachments/44247_APB_HealthCarePrograms.pdf

There are two main reasons that RBMs don’t work for patients. The first is that, because they lack physician buy-in and are imposed by a third party, most physicians choose to “game” RBM guidelines over time once they learn what “box to check” on the RBM form. This is why the existing literature on RBMs has shown that its impact on utilization tends to be transient. The second reason RBMs don’t work is that even when they do produce cost savings, it is merely because they have erected a wall of red tape that saves payers money while costing providers money through added busy work and lost time. It’s called the ‘sentinel effect.’ In other words, RBMs achieve profits for themselves through cost shifting rather than true healthcare value creation. See *Journal American College of Radiology* 2011;8:393-401.

What is Clinical Decision Support and how does it relate to Prior Authorization?

CDS is a set of evidence-based guidelines that are integrated into a physician’s own ordering system. This lets the doctor see in real time what imaging tests they should order, and prompts the doctor to order imaging tests more intelligently by showing them information such as the amount of radiation associated with each test. Through information transparency and user-

oriented design, CDS tools help physicians be more effective while preserving their autonomy.

Through decades of development at the top medical institutions in the world (e.g Massachusetts General, Virginia Mason Medical Center) it has been shown repeatedly that CDS-driven solutions improve the quality of care delivered to patients while simultaneously reducing healthcare costs. In fact, Congress’ embrace of clinical



decision support was due in large part to the successful CDS pilot efforts of the Institute of Clinical Systems Improvement (ICSI) in Minnesota:

https://www.icsi.org/about_icsi/legacy_work/diagnostic_imaging/icsis_work_is_basis_for_cms_move_to_decision_support/

CDS works so well that geographies that have pioneered its use have no use for RBMs. For example, forms of CDS are now accepted as an alternative to RBM prior authorization by Medicaid programs in Minnesota, Wisconsin and Maine. Despite the lack of a significant RBM presence in these geographies, patients in these areas have enjoyed more appropriate and less costly imaging since CDS was implemented - and physicians have welcomed the change.

Why are providers across the country implementing CDS on their own?

A variety of recent federal policy changes and CMS actions have increasingly aligned physicians with improving healthcare value by achieving reductions in the cost of care while improving objective measures of quality. The most celebrated examples include the formation of Accountable Care Organizations (ACOs), which have grown exponentially in number following passage of the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA), which ties future Medicare physician fee schedule rate increases to ACO participation. Because CDS is known to be an effective and physician-friendly way of improving care while decreasing costs, ACOs across the country are funding CDS implementation projects within their own electronic health records.



One last time - How exactly are CDS and RBM different?

The main difference is that physicians create and control CDS solutions whereas RBMs are third parties contracted by insurance companies to reduce imaging spend. You don't have to look any harder or farther than that to understand which solution is more aligned with the best interests of patients. But, to be helpful, the following summary is intended to highlight the key differences between these solutions.

RBM:

- Outside-in approach administered on behalf insurers
- Guidelines are opaque and proprietary and not even applied even-handedly
- Accomplishes savings for insurers through red tape and cost-shifting rather than value creation
- Known to be ineffective at improving imaging quality or decreasing net healthcare costs
- Detested by physicians and patients alike (as recent history has shown in Hawaii)
- Will not be accepted as an acceptable solution for PAMA regulations as noted above

CDS:

- Created and controlled by physicians and their non-profit medical societies
- Guidelines are evidence-based and transparent
- Works through empowering physicians and improving the care they deliver while preserving autonomy
- Shown to create true healthcare value and improve the quality of imaging
- Well-liked and widely adopted by physicians and health systems throughout the country
- Explicitly cited as an acceptable solution for the PAMA regulations noted above