September 24, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

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 Hospital Outpatient Prospective Payment (HOPPS) and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

The ACR provides comment on the following important issues:

1. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)
2. Low-dose CT Lung Cancer Screening
3. Radiology and Imaging Procedures and Services; Imaging Ambulatory Payment Classifications (APCs)
4. Payment Rates under the Physician Fee Schedule (PFS) Adjusted HOPPS for Items and Services Furnished by Excepted Off-Campus Provider-Based Departments of a Hospital
5. Proposed APC Placement of New and Revised CY 2019 Category I and III Current Procedural Terminology (CPT) Codes
6. Endovascular Revascularization Procedures
7. Movement of Brachytherapy and Stereotactic Radiosurgery (SRS) Procedures from Comprehensive-APCs (C-APCs) to Regular APCs
8. Moving C11 Choline off of the Pass-through List
9. Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers
10. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

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CT and MR Cost Centers

Proposal

CMS proposed to continue its transitional policy for another year to exclude providers that use the "square foot" allocation methodology for reporting costs for CT and MRI. Full implementation would not take place until calendar year (CY) 2020. CMS stated that they do not believe another extension in CY 2020 will be warranted and intend to determine the imaging APC relative payment weights for CY 2020 using cost data from all providers, regardless of the cost allocation method employed.

ACR Perspective and Comments

The ACR appreciates CMS recognizing that hospitals have not adequately moved away from using the "square foot" allocation method and offering another year's delay in fully implementing the CT and MRI cost data. However, we do not believe that an additional year will make CT and MRI payments more stable and ***ACR requests that for the FY 2019 HOPPS final rule, that CMS set weights based on a single diagnostic radiology CCR—the same policy that CMS applied before it created separate CT and MRI standard cost centers in 2011.*** The ACR makes this request based on evidence that the CCRs for CT and MRI are incorrect and are causing hospitals' payments for CT and MRI services to be too low. We thank CMS for the additional transition year, but ask that CMS terminate this policy as soon as possible because it does not appropriately reflect the costs associated with providing CT and MRI studies.

In February 2018, the ACR met with CMS officials and recommended the elimination of CT and MRI standard cost centers from both Inpatient Prospective Payment System (IPPS) and HOPPS and to return to the exclusive use of the diagnostic radiology CCR. ACR makes this request because of evidence that the original intent for the CCRs for CT and MRI to help eliminate cost compression within the imaging APCs is not being met.

Rationale for Separate Hospital Reporting of CT and MRI Cost Centers

CMS' policy on this issue was raised in the FY 2009 HOPPS rule where it discussed "a contract [awarded] to the Research Triangle Institute (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 services within cost centers."[1] 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 MRI and CT, the charge-compression hypothesis would set out to determine if higher cost diagnostic tests like MRI and CT have lower percentage mark-ups than lower cost X-ray tests. While MRI and CT

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

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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 false.*** However, it does not mean that the opposite is true—that MRI 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 costs centers is problematic than it does to conclude that CT and MRI 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.[2]

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 to set HOPPS rates until CY 2018, and now for CY 2019.

Policy Impact of Separating CT and MRI Cost Centers

Figure 1 below illustrates the trajectory of selected single procedure HOPPS rates for advanced and non-advanced imaging procedures. The CCRs for CT and MRI cost centers are inaccurate and too low and are depressing the valuation of APCs that include CT and MRI. The rate in CY 2017 under the HOPPS for CT 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. On its face, it does not make sense to pay the same for a CT as an ultrasound or an X-ray when a CT scanner is far more expensive than the ultrasound or X-ray equipment.

[2] FY 2009 IPPS Final Rule, page 48456.

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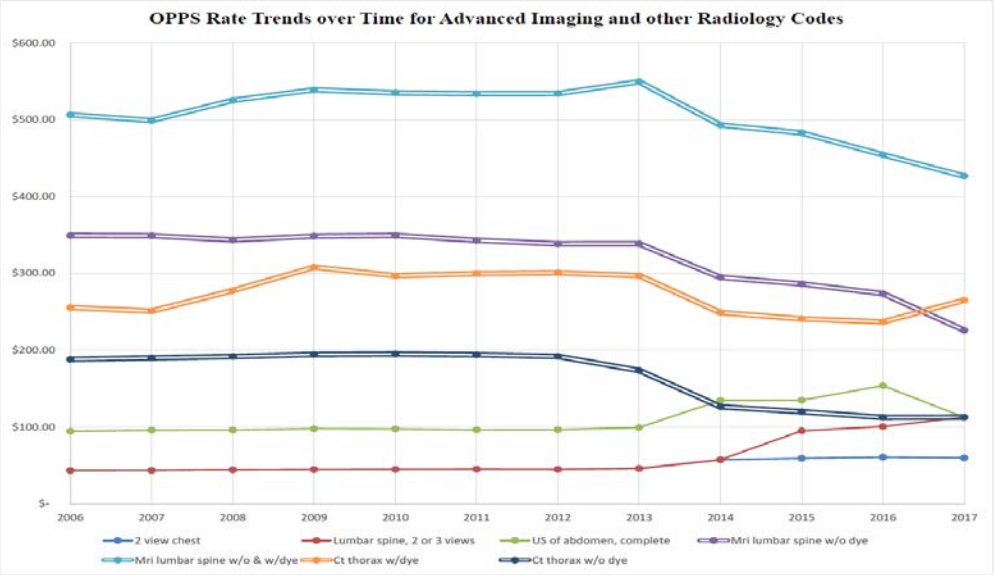
Figure 1. Trends in Rates for Selected Imaging Procedures: Advanced and Non-Advanced



The Problem is Getting Worse, Not Better

In the chart below, we show the hospital level billing practices for selected CT and MRI claims. These data show that only about half of all hospitals paid under the HOPPS had CT and/or MRI 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 2020 it is unlikely that more hospitals will have changed their cost reporting to the method preferred by CMS.***

The data in Chart 1 shows that hospitals have either been unable or unwilling to make the changes CMS regulations mandated.

HCPCS	Short Decriptor	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.

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Table 2 of the HOPPS proposed rule shows the CCRs that would be in use under the HOPPS if CMS uses all CCRs for the CT and MRI cost centers irrespective of the cost allocation method that the hospital is using. CT Scans have a CCR of 0.037 and MRI is 0.078.[3] 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. Although the number of valid CT and MRI CCRs has increased over time, they still would have a negative effect on the payment rates of almost all of the imaging APCs if all data regardless of cost allocation were used. In this proposed rule, this is the reason CMS states that you will provide another transition year because of stakeholders' concerns.

Table 2. CCR Statistical Values Based on Use of Different Cost Allocation Methods

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCD
All providers	0.0377	0.0527	0.0780	0.1046
Square Feet Only	0.0309	0.0475	0.0701	0.0954
Direct Assign	0.0553	0.0645	0.1058	0.1227
Dollar Value	0.0446	0.0592	0.0866	0.1166

Excerpts from the RTI Report suggest the data has been problematic from the start:

> "We were able to compute separately defined cost ratios for CT scanning in 25 percent of providers, and for MRI in 20 percent of providers, but in several of these the cost-to-charge ratios were so extremely low that it is likely that providers did not accumulate all of the costs, or possibly failed to identify allocation statistics to accumulate all of the indirect costs.[4]"

> "Many facilities had very low cost ratios on these nonstandard lines, including many below 0.05. This raises questions about the relative accuracy of their cost finding.[5]"

The requirement that hospitals create standard cost centers for CT and MRI is complex and hospitals are unable to respond. The CCRs for selected CT and MRI procedures 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 unable to accurately re-allocate many costs that are already allocated across hospital departments to new CT and MRI 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

[3] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model, Proposed Rule, July 31, 2018, page 37056.
[4] Whitehead, N., Kautter, J., Mosquin, P., Lynch, J., Squiers, L., Newman, L., . . . Coomer, N. (2008). Evaluation of the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration (Rep.). Waltham, MA: RTI International. Pg. 52
[5] Whitehead, N., Kautter, J., Mosquin, P., Lynch, J., Squiers, L., Newman, L., . . . Coomer, N. (2008). Evaluation of the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration (Rep.). Waltham, MA: RTI International. Pg. 65

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have not been moved. The presence of these near zero CCRs will contribute to underestimated costs used in rate setting, pulling rates for CT and MRI procedures down below their actual cost 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 hospitals to account CT and MRI 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 CT and MRI treating them differently from all other technologies.

Do Not Continue with the Planned Policy

The ACR's concerns are farther reaching than its effects to HOPPS. The use of separate CT and MRI CCRs created unintended consequences on the technical component of CT and MRI codes in the 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 HOPPS 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 OPPS methodology are fully justified. If payments are insufficient in the outpatient department and payments are lowered under the PFS to the HOPPS rate, access to advance imaging services will become a critical concern in all settings.

The ACR requests that for the FY 2019 HOPPS final rule, that CMS discontinue the regulatory requirement for hospitals to use the CT and MRI cost centers and instead set weights based on a single diagnostic radiology CCR—the same policy that CMS applied before it created separate CT and MRI standard cost centers in 2011.

Attachment I of this comment letter offers a technical document by which CMS could implement suspension of the CT and MRI cost centers and transition over to using the diagnostic radiology cost center for all imaging services under HOPPS.

CT Lung Cancer Screening Payment

Proposal

CMS proposes to continue to keep G0297 (low-dose CT for Lung Cancer Screening) in APC 5521 with a proposed 2019 payment rate of $62.86.

ACR Perspective and Comments

The ACR is disappointed that although CMS has 61,505 single claims in which to calculate the geometric mean for G0297 (low-dose CT for Lung Cancer Screening) that the hospital data still only allows for this preventative service to sit in in the lowest imaging without contrast APC (5521). The ACR conducted analysis, with the assistance of The Moran Company, to look further into the problems with this data. Our findings show that the calculated geometric mean cost using the CT cost center is $37.96. However, when the data is calculated using the diagnostic radiology cost center, the geometric mean cost increases to

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$96.55. We offer this as an example of how the ACR feels that the CT cost center is depressing payments for CTs and that it would be much more equitable if all imaging studies were instead calculated using the diagnostic radiology cost center.

Resultant Geometric Mean Costs for HCPCS G0297 When Utilizing Different Revenue Centers

Revenue Center Used in Calculation	Geometric Mean Cost
Using Current CCRs on Claims Used in Rate Setting	$ 37.96
Using Provider Specific Diagnostic Radiology CCR	$96.55
Percent Difference	154%

The ACR plans to conduct a study in the coming year to look at the effects of all CT and MRI codes as well as the structure of our APCs in order to present a plan for better payment stability.

Imaging Procedures and Services (APCs 5521 through 5524 and 5571 through 5573)

Proposal

CMS proposes to maintain the seven imaging APCs, which consist of four levels of imaging without contrast and three levels of imaging with contrast, and to make minor reassignments to the HCPCS codes within this series to resolve any violations of the 2 times rule. CMS invites public comments on whether CMS should maintain the current imaging APC structure, and on the related proposed HCPCS code reassignments.

ACR Perspective and Comments

Each year CMS uses its most current hospital outpatient data to calculate each imaging study's geometric mean and makes proposals of where these studies should sit within the APCs, and to verify code placements are in compliance with the two-times rule. The ACR and its consultants have evaluated the seven proposed imaging APC levels and have found that they include a total of 69 two-times rule violations. As you can see in Table 1 below, APC 5521 had a total of 45 violations and 5571 had 19 violations. Additionally, based on analysis conducted by The Moran Company, we identified nine different procedures with greater than 100,000 single procedure claims that are paid at less than 85% of their geometric mean costs.

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Table 1. Default APC Level Structure

APC	Geomean Costs	2-Times Rule Violations
5521	$64.02	45
5522	$115.89	3
5523	$236.05	2
5524	$502.75	-
5571	$206.94	19
5572	$395.84	-
5573	$699.02	-
Total Across Both Families	**n/a**	**69**

When reviewing the specific CPT codes that CMS proposes to move to higher or lower APCs as a result of their evaluation, ACR cannot make any recommendations within the current 7 imaging APC structure that does not still include a large number of two-times rule violations and cuts in payments for some studies by as much as 15%. As a result, none of our potential recommendations would offer payment or APC stability.

Therefore, we would like to take more time to consider how additional levels added to the imaging APC structure could provide long-term stability and eliminate the high number of codes that are in violation of the two-times rule. ***The ACR would like to work with CMS this coming year to investigate how to responsibly add more levels and thus stability to the imaging with and without contrast APCs.***

Proposed Comprehensive APCs

Proposal

For CY 2019, CMS proposes to add three C-APCs including C-APC 5163 (Level 3 ENT Procedures); C-APC 5183 (Level 3 Vascular Procedures); and C-APC 5184 (Level 4 Vascular Procedures). However, CMS does not propose to make any changes for cervical brachytherapy of which would either improve the C-APC 5715 or move these studies to regular APCs as we had requested earlier this year.

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Movement of Brachytherapy and SRS Procedures from C-APCs to Regular APCs

Background

Radiation oncology requires component coding to account for the multiple steps that comprise the process of care (consultation; preparing for treatment; medical radiation physics, dosimetry, treatment devices and special services; radiation treatment delivery; radiation treatment management; and follow-up care management). Cancer treatment is complex, as patients are often treated concurrently with different modalities of radiation therapy, combined with other specialty modalities, and often at different sites of service. The CMS C-APC methodology does not account for this complexity and fails to capture appropriately coded claims, resulting in distorted data leading to inaccurate payment rates that will jeopardize access to certain radiation therapy services if continued and expanded.

Brachytherapy

Brachytherapy for the treatment of cervical cancer is just one example that demonstrates how the C-APC methodology does not fully account for the complexities of cancer care. The standard of care for the nonsurgical curative management of cervical cancer includes concurrent chemotherapy with external beam radiation therapy (EBRT) and brachytherapy. Patients who receive this specific combination of treatment experience high quality outcomes, including longer survival times and lower mortality rates.

The 2018 Medicare HOPPS payment for cervical brachytherapy treatment is $2,272.61 which is:

- $13,731.51 less than the average cost for the brachytherapy portion of the treatment; and
- $40,000 less than the average cost for brachytherapy and external beam radiation therapy (partial treatment).

ACR Perspective and Comments

In late February, four major radiation oncology societies, including ACR, met with CMS to discuss concerns with the comprehensive (C-APC) methodology and its impact on radiation oncology payments.

The ACR requests that CMS:

- Revert to the traditional APC methodology for brachytherapy and radiation therapy services. If CMS insists on maintaining the C-APC methodology for these services, then the agency should:
    - Include the following in the C-APC 5414; 57155, 77470, 77370, 77771 and bundled services (e.g. port films, IGRT, supervision, handling loading of source and moderate sedation)
    - Assign to C-APC 5416 Level 6 Gynecologic Procedures
    - Allow for complexity adjustments
    - Separate payment for planning and preparation services, similar to the SRS policy
    - Separate payments for EBRT
    - Continue separate payment for brachytherapy sources
    - Align CMS' Repetitive Billing Instructions with HOPPS Methodology

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We believe these changes to the HOPPS methodology will begin to remedy the egregious underpayment for cervical cancer care. We also note that similar issue exists for other brachytherapy insertion procedures and urge the Agency to work with the radiation oncology specialty societies to remedy these payment disparities as well.

SRS

Background

In the CY 2016 HOPPS, CMS identified some, but not all, planning and preparation codes, and proposes continued separate payment in 2019 for the 10 codes associated with doing SRS listed below. In the 2016 HOPPS proposed rule, CMS recognized that the planning and preparation codes for SRS could be spread out over several days. This raised the problem of hospitals not being able to ensure that the set of codes related to the primary "J1" procedure could be captured in the C-APC methodology. CMS identified some, but not all, planning and preparation codes, and proposes continued separate payment in 2019 for the 10 codes listed below.

- CT localization (CPT 77011 and 77014)
- MRI imaging (CPT 70551, 70552 and 70553)
- Clinical treatment planning (CPT 77280, 77285, 77290 and 77295)
- Physics consultation (CPT 77336)

In the 2019 proposed rule, CMS maintains CPT 77371 and 77372 single sessions cranial SRS in Comprehensive APC 5627 Level 7 Radiation Therapy.

ACR Perspective and Comments

The College supports continued separate payment for the ten (10) planning and preparation codes related to CPT 77371 and 77372 for SRS. Additionally, we urge CMS to eliminate the C-APC payment policy for single-session stereotactic radiosurgery code 77371 and 77372. CMS should collaborate with stakeholders to develop a more appropriate payment methodology for these services.

Payment Rates under the PFS Relativity Adjustment HOPPS for Services Furnished by Excepted Off-Campus Provider-Based Departments of a Hospital

Proposal and Comment to Solicit a Method to Control for Unnecessary Services

CMS is concerned with the increase in the volume of outpatient services. As a result of this concern, CMS is proposing to use the authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS-adjusted HOPPS payment rate for nonexcepted items and services furnished by an excepted off-campus PBD (40 percent of the HOPPS) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines).

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Under this proposal, an excepted off-campus PBD would bill using the "PO" modifier in CY 2019, but the payment rate for services described by HCPCS code G0463 would now be paid at 40 percent of the HOPPS rate (the product of the full HOPPS rate and the PFS relativity adjuster).

ACR Perspective and Comments

The ACR opposes CMS expanding the off-campus policy to excepted sites which provide clinic visits billed under G0463. These sites are considered excluded from the Section 603 policy and further study should take place to verify that this growth is outside of the natural process of providing needs to the community.

Proposal

For CY 2019, CMS is also proposing that if an excepted off-campus PBD furnishes a service from a clinical family of services for which it did not previously furnish a service (and subsequently bill for that service) during a baseline period, services from this new clinical family of services would not be covered OPD services. Instead, services in the new clinical family of services would be paid under the PFS adjusted HOPPS (40 percent of the OPPS payment).

ACR Perspective and Comments

The ACR also opposes the proposed definition of using an imaging APC to define a family for new services. CMS seems to imply that clinical families are modality specific in this case. But there is no modality specificity or clinical similarity in APC families beyond "imaging". Therefore, if a site previously offered any imaging, then in theory any added service is not new.

Also CMS moves codes within these APCs every year. Therefore, in one year codes might get paid at 40% of HOPPS and others it may not. CMS' proposal does not offer a consistent and reliable definition of the clinical family by using the APC structure. ***The ACR supports the recommendations by the HOP Panel to not implement this proposed expansion of the off-campus site neutral policy until CMS studies the matter to better understand the reason for increased utilization of services.***

Proposal

CMS is also interested in other methods to control for unnecessary increases in the volume of outpatient services. Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?

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How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency?

Could utilization management help reduce the overuse of inappropriate or unnecessary services?

ACR Perspective and Comments

The ACR believes that utilization management would help to reduce the inappropriate use of services in the hospital outpatient setting. For radiology this issue will be addressed by the implementation of clinical decision support (CDS) as mandated by PAMA. This utilization management tool uses evidence-based appropriate use criteria to determine which imaging study, if any, is the right diagnostic test for the patient. This policy is due to begin implementation as of January 1, 2020. Although this policy is being discussed in detail in the physician fee schedule proposed rule, this policy will also affect emergency departments and services provided in the hospital outpatient setting.

Proposal

For what reasons might it ever be appropriate to pay a higher HOPPS rate for services that can be performed in lower cost settings?

ACR Perspective and Comments

CMS should pay higher HOPPS rates in the hospital outpatient setting because hospitals have added costs such as meet health and safety rules, have to be open longer and provide a greater variety of services than physician offices. The hospital outpatient payments are based on hospital charges and cost data. ***If the costs reported by hospitals are higher, then they should receive the higher payment to cover those costs.***

Proposed APC Placement of New and Revised CY 2019 Category I and III CPT Codes

Proposal

CMS included proposed APC placement of new and revised CY 2019 Category I and III CPT codes in Addendum B with a "NI" modifier indicator.

ACR Perspective and Comments

In March 2018, ACR met with CMS and made recommendations for APC placement of the new 2019 radiology-related CPT codes. CMS accepted all of ACR's recommendation, except for three codes; 10X16, 10X18, and 50X39. ***We thank CMS for agreeing with most of ACR's recommendations.***

ACR proposes that CPT code 10X16 (Fine needle aspiration biopsy, including CT guidance, first lesion) be placed in APC 5072 (Level 2 Excision/ Biopsy/ Incision and Drainage). Instead CMS has proposed to place the code in 5071 (Level 1 Excision/ Biopsy/ Incision and Drainage). ACR believes that 5071 is not the appropriate placement of 10X16 because the resource use of CT guidance is much higher than

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fluoroscopy or ultrasound. Therefore, this code should be placed with other codes that also frequently use CT guidance.

Additionally, CMS proposed to place CPT code 10X18 (Fine needle aspiration biopsy, including MRI guidance, first lesion) in 5071 (Level 1 Excision/ Biopsy/ Incision and Drainage). ACR believes that the resource use of MRI guidance as described in 10X18 is more clinically similar to the codes in APC 5373 (Level 3 Urology and Related Services).

Finally, CMS proposes to place code 50X39 (Introduction of guide into renal pelvis and/or ureter with dilatation to establish nephrostomy tract, percutaneous, including imaging guidance, radiological supervision and interpretation and post procedure tube placement) in APC 5473 (Level 3 Urology and Related Services). ACR recommended that 50X39 be placed in APC 5474 (Level 4 Urology and Related Services) because of the much higher resource use due to the bundling of imaging guidance, radiologist supervision and interpretation (RS&I) and post procedure tube placement.

Below are ACR's recommended APC placements for codes 10X16, 10X18 and 50X39 for the CY 2019 final rule:

New and Revised CY 2019 Category I and III CPT Codes

New Code	Short Descriptor	CMS Proposed APC	ACR APC Recommendation
10X16	**Fna bx w/ct gdn 1st les**	**5071**	**5072**
10X18	**Fna bx w/mr gdn 1st les**	**5071**	**5373**
50X39	**Dilat xst trc ndurlgc px**	**5373**	**5374**

Endovascular Revascularization Procedures

Proposal

CMS asked for stakeholder comments on expanding the C-APCs for endovascular revascularization from four levels to as many as six levels. CMS acknowledged previous stakeholder comments stated that certain procedures, such as angioplasty procedures with use of a drug-coated balloon in addition to a non-coated balloon, have significantly higher resource costs than the geometric mean cost for all angioplasty procedures combined.

ACR Perspective and Comments

The ACR and its consultants analyzed the endovascular revascularization C-APCs. We found that there are not any codes with two times rule violations in these APCs. The ACR appreciates that CMS would consider creating additional levels but ACR does not support expanding the endovascular revascularization C-APCs at this time because we do not see a specific benefit in doing so. Table 3 below shows the current endovascular revascularization APC structure contains no two-times rule violations.

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Table 3 Current Endovascular APC Level Structures

APC	Geomean Costs	2-Times Rule Violations
5191	$2,882	-
5192	$4,843	-
5193	$9,945	-
5194	$15,789	-
Total	**n/a**	**-**

ACR would like to reserve the opportunity to ask for additional C-APC levels for endovascular revascularization until there is data that shows additional levels are necessary to provide stabilization or improve payment accuracy.

Moving C11 Choline off of the Pass-through List

Proposal

CMS proposes to remove HCPCS code A9515 (Choline C 11, diagnostic, per study dose) off the transitional pass-through payments for a drug or biological list. A9515 (Choline C 11, diagnostic, per study dose) was placed on pass-through payment in April 2016.

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2018 Status Indicator	CY 2018 APC	Pass- Through Payment Effective Date
A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016

In the CY 2017 HOPPS final rule, CMS finalized a policy that allowed pass-through payments to expire on a quarterly basis for newly approved pass-through drugs, biologicals and radiopharmaceuticals approved in CY 2017 and subsequent calendar years. This policy affords a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

ACR Perspective and Comments

ACR believes that CMS should continue A9515 on pass-through payment status until it reaches the full three-year period. Allowing for A9515 to maintain pass-through status will allow CMS to gather more robust cost data associated with A9515.

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Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the FY 2019 IPPS proposed rule, the CMS request stakeholder comments on various policies relating to interoperability and health information exchange. Again, the ACR supports CMS' goal of advancing health information exchange via the requirements for eligible hospitals in the Promoting Interoperability (PI) Program. To that end, we agree with CMS' suggestion that hospital participation in the Office of the National Coordinator for Health IT's Trusted Exchange Framework and Common Agreement (TEFCA) could potentially be used in future years of the program for credit towards the PI score. This concept should be revisited in detail after TEFCA is launched and relatively established—perhaps as early as the 2020 IPPS rulemaking cycle.

More importantly, the ACR recommends that CMS leverage the PI Program to incentivize hospitals to facilitate appropriate health information exchange between their certified EHR technology (CEHRT) and the heath IT systems used by external medical imaging providers. Referring clinicians who use hospital CEHRT should be empowered to order studies from imaging providers of their choice (including the hospital's competitors), and to seamlessly receive and incorporate the resultant radiology reports/data into the EHR.

We understand these activities are, in part, addressed by the interoperability requirements in the "EHR exception/safe harbor" from self-referral/anti-kickback rules, as well as the future "information blocking" prohibitions mandated by Sec. 4004 of the 21st Century Cures Act. However, given CMS' enhanced focus on interoperability, it would be appropriate for Office of the Inspector General-determined violations of either a) the EHR exception/safe harbor requirements; or, b) the Cures-mandated information blocking prohibitions to also result in a hospital's failure of the PI Program.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

The ACR applauds the overarching effort by the Centers for Medicare and Medicaid Services (CMS) to improve patient accessibility and usability of charge information hospitals are required to post on the Internet under Section 2718(e) of the Public Health Service Act. The College supports the new mandate to post this previously required hospital charge information in a machine readable format, as well. Yet, the College questions any perceived connection between the need to increase hospital price transparency and alleviating so-called "surprise bills," or patients receiving care from physicians, such as radiologists, who are out-of-network but located at in-network facilities. In short, ACR believes that:

- Issues surrounding "surprise billing" are not a Medicare problem but rather a concept involving private insurance and, as a result, is best regulated by state legislatures;
- It is improper to place exclusive or even majority blame on the providers as the payors must have accountability for the products they are selling (without proper disclosure) and the aggressive contracting they employ;
- The term "surprise gaps in insurance coverage" is a better summary of the issue; and

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- Any discussion of "surprise bills" is largely inapplicable to Medicare and outside-the-scope-of the HOPPS rulemaking process.

More specific comments regarding these topics can be found below:

ACR continues to favor steps to enhance transparency regarding the cost of health care, including advanced diagnostic imaging services, administered in the hospital and all other care settings. The ACR is supportive of provisions originally enacted via the CY 2015 Inpatient Prospective Payment System (IPPS) Final Rule (79 FR 50146) requiring hospitals to make public either a list of charges (either the chargemaster itself or in another form of their choice) for provided items and services or their policies for allowing the public to view prices in response to a patient inquiry. While this concept is not up for consideration in the CY 2019 HOPPS proposed rule, the College also supports new provisions in the CY 2019 IPPS Final Rule mandating hospitals post the charges in a machine readable format. ACR shares CMS's view that patients are more inclined to choose the most efficient setting for care if they are more conscious of its underlying expense. Choice, however, must remain a two-way concept and patients, in consultation with their treating physician, should retain the ability to pursue the care they feel best suits their clinical needs, even if it means selecting the more expensive setting.

Despite our support for greater price transparency, the College is perplexed why CMS included provisions in the 2019 HOPPS Proposed Rule stating their concern that insufficient access to price transparency information is contributing to patients being surprised by out-of-network bills for physicians, such as radiologists, at in-network hospitals and other settings. **First and foremost, ACR questions any true connection between the issue of "surprise bills" and Medicare. "**Surprise bills" typically arise when an individual receives planned care from an in-network provider but other providers brought in to participate in the patient's care do not participate in the same network. The ramifications for patients seeing out-of-network physicians at an in-network facility are typically higher cost-sharing (e.g. copayments, coinsurance, and deductibles) and balance bills, or treating providers billing individuals directly for the remaining cost of the service rendered above the negotiated rate assessed by the insurance company to in-network providers.

The College, however, views "surprise bills" as an issue largely stemming from the actions of private insurers and not government payors. In fact, Medicare classifies practitioners into three categories: participating, nonparticipating, or opt out/private contracting providers. According to briefs published on the web sites of the AARP and Kaiser Family Foundation, as many as 95 percent of Medicare physicians are participating providers[6][7]. This classification means they agree to accept Medicare's approved payment as payment in-full (e.g. "accept assignment") for the Medicare covered services they provide for *all* Medicare patients they see. In addition, they must also collect payment from services rendered directly from Medicare, rather than the patient. As a result, Medicare patients who see a "participating provider" are

[6] AARP (2017) Fact Sheet: Medicare's Financial Protections for Consumers: Limits on Balance Billing and Private Contracting by Physicians. Retrieved from https://www.aarp.org/content/dam/aarp/ppi/2017-01/medicare-limits-on-balance-billing-and-private-contracting-ppi.pdf

[7] Kaiser Family Foundation (2016) Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services. Retrieved from https://www.kff.org/medicare/issue-brief/paying-a-visit-to-the-doctor-current-financial-protections-for-medicare-patients-when-receiving-physician-services/

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guaranteed to not be charged more than the published fee-schedule amount, nor will they face higher out-of-pocket cost-sharing above the standard 20 percent coinsurance for the service received.

Only a small percentage of providers, approximately 4 percent, are classified as nonparticipating Medicare physicians[8]. Nonparticipating physicians only receive 95 percent of the Medicare payment reimbursed to participating providers. In addition, nonparticipating physicians can only balance bill patients based off of payment rates that are no more than 115 percent above Medicare's established fee-for-service rates. While patients seen by nonparticipating providers are still assessed a 20 percent coinsurance, it is calculated based off of 95 percent of Medicare's established fee-for-service amount. The stipulations placed on the amount nonparticipating providers can charge Medicare patients have successfully limited the negative impact of "surprise out-of-network bills." In fact, total out-of-pocket liability from balance billing declined from $2.5 billion in 1983 to $40 million in 2011[9].

An even smaller percentage of providers, approximately less than 1 percent, are classified as opt-out or private contracting providers[10]. In 2016, of this 1 percent, 42 percent of opt out physicians were psychiatrists[11]. In fact, 2013 data indicates in the specialties of radiology/nuclear medicine, only 19 out of a possible 24,887 radiologists, were opt-out/private contracting providers within Medicare.[12] In other words, radiology and nuclear medicine only comprised 0.1% of the total opt-out/private contracting population in 2013. Although this category of providers is not bound by Medicare's physician fee schedule in any way and are free to balance bill for the entire cost of the service, there are so few opt-out/private contracting physicians that it has an almost minimal impact on the current system. Further, beneficiaries engaging in private contracts with opt-out physicians are agreeing that the physician will not be bound by Medicare's rate structure and will pay the full charge and not submit the claim to Medicare.

Since the vast majority of providers are classified as "participating," there's almost no tangible concern about "surprise out-of-network bills" from any physician, including radiologists, in Medicare. Plus, the strict limitations on balance billing placed on nonparticipating Medicare providers, as well as the extremely small percentage of total opt-out/private contracting physicians, further lessens the concerns pertaining to this issue.

Finally, the College views the term "surprise bills" as overly biased against physicians and mischaracterizes the role of the insurer. Private payors are quick to shift the blame for excessive out-of-network bills to physicians when, in reality, "surprise bills" are "surprise coverage gaps" typically associated with cheap insurance plans and inadequate provider networks. As a result, it's more accurate to

[8] Kaiser Family Foundations (2016) Surprise Medical Bills. Retrieved from https://www.kff.org/private-insurance/issue-brief/surprise-medical-bills/
[9] Kaiser Family Foundations (2016) Surprise Medical Bills. Retrieved from https://www.kff.org/private-insurance/issue-brief/surprise-medical-bills/
[10] Kaiser Family Foundation (2016) Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services.
[11] Kaiser Family Foundation (2016) Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services.
[12] Kaiser Family Foundation (2016) Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services.

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associate "surprise bills" with insurers preying upon consumers' desire for low-cost insurance, as well as private payors failing to disclose potentially costly flaws in their plans.

In summary, ACR questions the exposure of patients to "surprise out-of-network bills" within Medicare. Issues pertaining to out-of-network bills are the result of private payors and, as a result, any policy proposals are best dealt with at the state level. Furthermore, the College believes this policy concept is outside-of-the-scope of the OPPS proposed rule and we question the validity of trying to address any perceived problems in this manner.

Thank you for the opportunity to comment on the proposed rule. We hope you find these comments provide valuable input for your consideration. 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 or Christina Berry at 800-227-5463 ext 5909 or via email at cberry@acr.org.

Respectfully Submitted,

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Attachment I: ACR Process by Which CMS Could Implement Suspension of CT and MR Cost Centers

Policy:

Cease to utilize separate CT and MR standard cost centers for calculation of "cost" in IPPS rate setting and for calculation of rates in HOPPS rate setting for 2019. Given the inaccurate reporting of costs for CT and MR, merging the CT and MR cost centers into diagnostic radiology will solve the problem ACR has identified. The below suggest interim steps to improve payment accuracy until CMS has accurate data from hospitals reporting all costs in the diagnostic radiology cost center rather than splitting costs into diagnostic radiology, CT and MR.

Implementation:

- CMS would change its "revenue code to hospital cost center crosswalk" to map the revenue codes for CT and MRI to the department cost center for diagnostic radiology.
- In programming the "cost" calculation (reduction of charges to cost by multiplying the charge on the claim by the cost-to-charge ratio for the hospital department to which the revenue code maps), CMS should replace all CT and MRI cost-to-charge ratios by the cost-to-charge ratio for diagnostic radiology.
- In the IPPS, CMS should calculate the diagnostic radiology cost-to charge ratio excluding all data tied to CT and MRI revenue codes. The CT and MR cost centers have been shown to have highly inconsistent and often unbelievable data.
- In the OPPS, CMS should simply replace the CT and MRI cost-to-charge ratio with each hospitals' diagnostic radiology cost-to-charge ratio.
- CMS would then set rates in both payment systems based on the diagnostic radiology cost center.
- Hospitals would be advised through regulation and cost reporting instructions to no longer report costs separately for CT and MRI with a recommendation that hospitals review the completeness of their reporting diagnostic radiology cost inclusive of CT and MR equipment, space, labor, and other cost factors.
- Hospitals may continue to use CT and MRI revenue codes. The revenue code to hospital departmental cost center cross-walk will continue to map CT and MRI revenue codes to diagnostic radiology in future years.

Benefit to Hospitals:

- Encourages consistent accounting for different and evolving technology and delivery systems used by hospitals for diagnostic radiology.
- Frees hospitals to account for high cost medical equipment in a manner consistent with standard accounting principles.
- Simplifies and standardizes reporting of cost within the diagnostic radiology cost center for Medicare rate setting, and over time, should eliminate the distortions in the partial allocation of cost to CT and MRI cost centers that had resulted from the requirement.

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- Reduces burden on accounting practices.

Policy Impact:

- Reinstates realistic differentiation in diagnostic radiology between standard and advanced imaging technologies: hospitals will report difference in valuation based on charges.
- Will allow CMS to reevaluate diagnostic radiology APC structure based on more accurate geometric mean costs for CT and MRI.
- Stops undervaluing the cost of CT and MRI technology that has led to compressed advanced imaging rates into the range of lower cost imaging technologies.
- Reduces burden on hospitals.
- Reduces error and inaccuracy in hospital cost reporting data.
- Stabilizes rates in HOPPS consistent with site neutral payment policies and the physician fee schedule going forward.

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