



September 6, 2016

Andy Slavitt
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule

Dear Acting Administrator Slavitt:

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 on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Hospital Outpatient Prospective Payment System (HOPPS) and Quality Reporting Programs.

The ACR provides comment on the following important issues:

- 1) APC Restructure of Diagnostic Radiology
- 2) Potential Unintended Consequences of Reliance on Resource Use Simplified to Geometric Means without other Considerations to Determine APC Placements
- 3) Proposed Treatment of New and Revised CY 2017 Category I and III CPT Codes That Will Be Effective Jan. 1, 2017
- 4) Proposed Changes to Packaged Items and Services
- 5) Proposed Expansion of the C-APCs
- 6) Proposal to Change the Beginning Eligibility Date for Device Pass-Through Payment Status
- 7) Site Neutral Payments
- 8) Changes for Payment for Film X-Ray
- 9) Appropriate Use Criteria for Advanced Diagnostic Imaging Services

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- 10) Imaging Efficiency Measures
- 11) EHR Provisions
- 12) Technical Appendix: Request for Greater Transparency and Documentation of New Policies

APC Restructure of Diagnostic Radiology

In this proposed rule, CMS is proposing to consolidate the CY 2016 radiology-related APCs from 17 to 8. The ACR appreciates CMS' attempt at restructuring the Diagnostic Radiology APC family into a more coherent and sustainable structure, however we have several major concerns, including:

- 1) Lack of Explanation and Transparency of the Extensive Restructuring of the APCs this year;
- 2) Lack of "clinical similarity" as embodied in the Congressional intent that the APCs be based on both clinical similarity and resource similarity;
- 3) Potential Unintended Consequences of Reliance on Resource Use to Determine APC Placements
- 4) ACR Proposed Restructure of the Diagnostic Radiology APCs

Lack of Explanation and Transparency of the Extensive Restructure

In this proposed rule, CMS proposes another extensive consolidation and restructure of diagnostic imaging services but does not explain the intent of this restructure. CMS also eliminates entire APC families and moves hundreds of codes into different APC families, but does not mention these changes or provide rationale. When CMS proposed a broad APC restructure for 2016, there was an explanation of the intent and rationale. Based on the rationale for changes in the 2016 rule, ACR worked with CMS last year to organize the radiology studies in a clinically coherent and constructive way. The lack of transparency in the 2017 proposed rule makes it difficult to understand what CMS' intentions are. The structure proposed in this rule is not at all consistent with the ACR proposal. Proposing a completely different structure including a multitude of codes from other clinical families makes it difficult for us to make constructive comments. (See attached Technical Appendix)

Lack of Clinical Similarity within APCs

As CMS continues to collapse APCs into fewer APCs each with more CPT codes, the ACR feels the lack of clinical similarity becomes a significant shortcoming. "Clinical

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similarity," as embodied in the Congressional intent, mandates that the APCs be based on both clinical similarity and with respect to resource use.

The original legislative mandate under which the OPSS was created states that, (B) the Secretary may establish groups of covered outpatient department (OPD) services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified within the group that includes the service to which the item relates;

The intent of the language was to preserve clinical similarity per the mandate. According to our legislative experts, the fact that clinical similarity is listed first should be interpreted to mean that the intent of Congress was to emphasize that clinical similarity is the more important element. Looking at one APC at a time, or one APC family, now appears to be without clinical context.

In the April 7, 2000 HOPSS final rule HCFA states "The definition of each APC group should be "clinically meaningful," that is, the procedures or services included within the APC group relate generally to a common organ system or etiology, have the same degree of extensiveness, and utilize the same method of treatment, for example, surgical, endoscopic, etc." To some extent, CMS' continued efforts to collapse the APC structure was destined to cause issues with maintaining clinical similarity. A decline in the number of APC's means that the context in which each code relates to one another expands and the relationship between those procedures becomes less specific and meaningful. It is worth noting that while continued efforts in packaging lend to CMS's goal of creating a "more prospective payment system", collapsing the structure of the APC's does not necessarily do the same.

Congress intended for HCPCS codes to be placed in APCs with major consideration given to their clinical similarity. The ACR strongly believes that radiology, cardiology and all other specialty codes should continue to map to their own clinical families until such time that CMS can articulate a clear concept and criteria for an alternative approach to clinical similarity consistent with the intent of the statute. Note that CMS conceded to the Nuclear Medicine specialists to keep its APC separate from Diagnostic Radiology, which is much more clinically similar to Diagnostic Radiology than is Diagnostic Cardiology. These two approaches in the proposed restructured APC system seem contradictory.

For Example:

- CMS proposes to eliminate the conventional APC family for diagnostic cardiology and move it into a new Level I for the Endovascular Family, making it

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a C-APC. All but one code in the old diagnostic cardiology family was moved to this new APC. CMS does not explain this change in the proposed rule.

- Currently G0105 and G0121 are colonoscopy codes in APC 5312 (Lower GI Procedures). CMS proposed to place these two codes in APC 5525 (Level 5 Diagnostic Radiology without Contrast). These codes are not clinically similar or resource similar to diagnostic imaging procedures. G0105 and G0121 are colonoscopy codes, involving placing a colonoscope into the patient's colon, typically done by a gastroenterologist and rarely if ever performed by a radiologist.
- Currently the echocardiogram codes are in APC 5561 (Echocardiogram with Contrast). CMS proposed to place these codes in APC 5573 (Level 3 Diagnostic Radiology with Contrast). C8922-C8930 are trans-esophageal cardiac US codes. Trans-esophageal studies involve placing an ultrasound probe into the esophagus to visualize the heart and great vessels. A Cardiologist performs this procedure, using a specialized ultrasound (US) system requiring patient sedation and monitoring (typically with a nurse present). The cardiac US exams are processed and interpreted using cardiac US software, separate workstations and Cardiology PACS, often independent of the Radiology PACS and workstations (due to need for advanced and specialty specific software and hardware). Cardiologists supervise and interpret these exams. These exams are not clinically similar or resource similar to the diagnostic radiology codes. In addition, the contrast used in these exams are microbubble agents, not the typical iodine based vascular contrast agents used in CT or the gadolinium based agents used in MRI.

Proposed Exception to the 2 Times Rule for APC 5521

CMS proposes an exception to the 2 times rule for APC 5521 (Table 9 in the proposed rule). However, CMS does not provide any explanation for the exception to the 2 times rule.

The ACR requests CMS provide any or all explanations for exceptions to the 2 times rule that affect diagnostic radiology APCs.

Potential Unintended Consequences of Reliance on Resource Use Simplified to Geometric Means without other Considerations to Determine APC Placements

It appears that CMS demonstrates less consideration for clinical coherence year-to-year and proposes categorizing codes according to resource use based almost exclusively on their geometric mean. The expansiveness of these changes suggest that CMS may continue to head further in this direction in the future, raising increased uncertainty about the stability of hospital outpatient payments from year-to-year. Once studies are placed

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into APCs almost exclusively according to their calculated geometric mean, the volatility of the data from year-to-year will cause constant movement of these codes from level to level and in some cases from APC family to APC family. We observe considerable volatility in payment rates from 2016 to the proposed 2017 rates and experienced significant volatility with the 2016 re-organizations. (See the attached Technical Appendix for further discussion)

For Example:

Low-dose Lung Cancer Screening - APC 5521 (Level 1 Diagnostic Radiology without Contrast)

CMS’ proposed restructure produces devastating cuts to the new CT Lung codes. The ACR is alarmed that CMS’ proposed reimbursement rates for both G0296 (Shared Decision-Making Session) and G0297 (Low-Dose Lung Cancer Screening) result in such steep cuts. CMS cited the 2015 geometric mean cost data for both the shared decision-making visit and LDCT screen as justification for the assignment of these two codes to a Level 1 Ambulatory Payment Classification (APC). Currently classified in Level 2 APCs both G0296 and G0297 are grouped with other services that have a geometric mean cost of \$110. In comparison, services grouped within a Level 1 APC have a geometric mean cost of \$63 as shown in the chart below:

HCPCS Code	Descriptor	2016 APC	2016 Payment	2017 APC	2017 Payment	Dollar Difference	% Change
G0296	LDCT-LCS Shared Decision-making Session	5822	\$ 69.65	5821	\$ 25.09	-44.56	-64%
G0297	Low-dose Lung Cancer Screening	5570	\$ 112.49	5521	\$ 63.33	-49.16	-44%

The primary issue is that hospitals have not had time to appropriately set charges in claims that reflect full cost of these codes. Only 40 single claims can be identified in the 2015 OPPS claims data for G0297. Given the nature of this new screening program, these studies need at least two full years for hospitals to establish the programs and report appropriate costs.

Therefore temporary placement should be at the ACR recommended levels for 2017 and possibly, 2018.

By proposing these lower payment rates, CMS fails to recognize the enormous time and effort involved in these studies. For the shared decision-making session, the patient is evaluated for screening eligibility, advised of the screening process and smoking cessation options. The low-dose CT study includes extra steps beyond a CT thorax without contrast (71250) utilizing structured reporting materials, reporting clinical findings and patient information to data registries. The resources involved in G0297 are

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greater than those of a CT thorax, which is proposed to be placed in the Level 2 Diagnostic Radiology without Contrast APC at \$117.40.

The ACR requests that CMS continue the APC placements of G0296 and G0297 in their CY 2016 Level II APC assignments of 5582 and 5570, respectively for CY 2017 and CY 2018, or in resource-comparable APCs until sufficient experience with these new programs generates the expected volume of services as the basis for future rate setting.

If CMS chooses not to delay implementation of the proposed 2017 APC structure to allow for full explanation and meaningful comment, then ACR offers an alternative Diagnostic Radiology Family Structure that implements our view of clinical similarity, resource similarity, recognizes CMS's need to separate APC families with certain contrast procedure codes from all other radiology procedure codes, and integrates the approach ACR originally proposed to CMS earlier this year. This structure is described fully below, and an Excel Workbook accompanies this letter as an attachment showing the proposed placement of all diagnostic radiology codes that ACR has determined belong in a clinically similar family.

Placement of HCPCS Code 75571 by CMS into Level 1

Procedure code 75571 (CT heart, without contrast, with quantitative evaluation and coronary calcium) had a published geometric mean cost of \$13 in the 2016 Final Rule. The calculated geometric mean cost for 75571 for 2017 is \$23. The ACR's believes that hospitals are not correctly reporting costs for this procedure. This procedure requires greater resources than 72128 (CT chest spine w/o dye) that has a geometric mean cost of \$128, so it is believed that the calculated \$13 and \$23 geometric mean cost for 75571 cannot be accurate.

In spring 2016, ACR suggested that HCPCS code 75571 (*Ct hrt w/o dye w/ca test*) be placed into a Level 3 category due to clinical similarity. CMS did not accept this proposal and instead placed the code into APC 5521 (Level 1 Diagnostic Radiology) without explanation.

The ACR requests that this code be placed in in a higher APC Level for 2017 and requests a waiver of the two-times rule to support such placement.

Severe Cuts in MR and CT in the Physician Fee Schedule because of DRA

The ACR is extremely concerned about the devastating cuts that will take place to the technical component of MR services in the 2017 physician fee schedule because of CMS' proposed diagnostic radiology restructure.

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For example:

- MR codes that are proposed to be placed in APC 5571 are cut by 39% in their APC payments which has a rippling effect of a -19% in the technical component of these codes in the proposed 2017 physician fee schedule.

These cuts are unsustainable for radiology practices that have had their technical components continuously reduced by Congressional and CMS policies since 2006. There are potentially many critical unintended consequences of CMS solely relying on resource use to determine the APC or C-APC placement of HCPCS code representing medical studies. Almost exclusive reliance on the geometric mean as the embodiment of resource similarity does not take into consideration other elements that affect the uniqueness of clinical specialties such as specialized facilities, staff and training. Below are examples of impacts we are seeing from the proposed movement of diagnostic radiology codes into a new structure. These cuts are significant and not something ACR can support:

CT and CTA of the pelvis with, with&w/o dye (-60%)
CT Colonography (-44%)
LDCT lung cancer screening (-44%)
MRI and MRA with contrast (-39%)
X-ray and DXA (-37%)
Ultrasound of the breast, OB, pelvis, transvaginal, fetal (-31%, -24%)
MRI/MRA without dye (-20%)
Other Impacts:
LDCT-LCS Shared Decision-making (-64%)
DRA impacts on MRI services in the proposed PFS (-19%)

The attached Technical Appendix discusses in further detail the ramifications of major changes in payment rates because of APC volatility, including how such volatility and un-anticipated/unexplained change can and will affect hospital finances: hospitals will likely only see a lag in their revenues, which will affect planning, budgeting and negotiations. Hospitals are not provided adequate time for their departmental structures to process and adapt to this level of unexplained change.

The ACR is opposed to CMS categorizing HCPCS codes in APCs with respect to resource use without clear criteria for clinical similarity. Based on our analysis, the apparent lack of consideration for clinical similarity will cause the availability of vital services such as CT lung screening and cardiac calcium scoring to disappear from the hospital outpatient setting.

In addition, the rippling effects of the cuts to the payment rates of MR and CT codes will not only cause radiology offices to no longer be able to provide these services to

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Medicare FFS beneficiaries, but hospital outpatient departments will not be able to cover their costs either in OPSS or under CMS' proposed site-neutral policy.

CMS must use its authority to override the two times rule and other exceptions to maintain the integrity of OPSS and allow for flexibility when hospital data for these types of important studies fall short and also provide corresponding explanation when this happens.

ACR Proposed Restructure of the Diagnostic Radiology APCs

In anticipation of CMS' goal of further consolidating studies into fewer APCs, the ACR did a study earlier this year to determine if this could be accomplished for the diagnostic radiology family while still maintaining stable payment levels. As CMS alludes to in the proposed rule, the ACR met with CMS earlier this year and recommended a restructure which would have consolidated the 17 existing imaging APCs to 9. The purpose of ACR's proactive move was to keep radiology together within its own family and to re-categorize its APCs to be more clinically similar with respect to resource use. The ACR did not insist that CMS move toward aggressive consolidation for CY 2017 but offered a model for consideration for when CMS chose to move in that direction.

The ACR was surprised to discover that CMS placed the diagnostic radiology services into 8 new categories, the contents of which are a major departure from what ACR recommended. CMS's model not only reorganizes the radiology APCs based on whether studies are done with contrast or without contrast (a statutory requirement that the ACR proposal implemented in a different way), but also mixes in studies from several other specialties. In addition, CMS offers virtually no explanation as to the intent of their proposal nor do they explain why our recommendation was not accepted. The ACR put considerable thought, time and resources into our proposal and we want to know the reasoning behind CMS' decisions.

- In this proposed rule, CMS decided to exclude the nuclear medicine codes from this restructure and maintains them in their own separate APCs. We also understand that the nuclear medicine community would like to keep its set of codes in their own family of APCs. ***The ACR is in support of this proposal.***
- In ACR's original proposal, we recommended that interventional radiology imaging studies shift to the vascular family. In this proposed rule, CMS removes interventional radiology imaging studies from the diagnostic radiology APCs and proposes to place them in the vascular family. ***The ACR is in support of this proposal.***
- Regarding the 2017 Vascular APCs, CMS proposes that MRI of the brain w/o & w/dye (code 70559) be moved from CY 2016 APC 5526 to vascular procedures

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APC 5181. This placement does not make clinical sense. The ACR recommends that this code be placed with the other MR with and w/o contrast codes for the CY 2017 final rule.

70559	Mri brain w/o & w/dye	5526	Xray	5181	Vascular Procedures
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The proposed alternative structure for two Diagnostic Radiology Families is shown below for two families, one with 3 levels for certain contrast procedures, and one with 6 levels for all other procedures. The Excel Workbook Appendix to this letter includes the code level assignments for the proposed structure.

ACR Proposed Alternative Diagnostic Radiology APC Family with Contrast

APC	CMS			ACR Alternative	
	Payment Rate	Single Frequency	Geometric Mean Cost	Single Claim Count	Geometric Mean Cost
5571	\$278.87	885,319	\$291.46	455,847	\$ 242.49
5572	\$467.39	511,047	\$488.49	484,767	\$ 362.70
5573	\$777.31	39,497	\$812.40	409,267	\$ 487.63

ACR Proposed Alternative Diagnostic Radiology APC Family All Other Procedures (not in Contrast Family)

APC	CMS			ACR		
	Payment Rate	Single Frequency	Geometric Mean Cost	APC	Single Claim Count	Geometric Mean Cost
5521	\$63.33	6,415,811	\$66.19	5521	5,261,480	\$ 61.95
5522	\$117.40	4,413,585	\$122.70	5522	3,672,895	\$ 106.07
5523	\$218.74	2,054,383	\$228.62	5523	2,120,254	\$ 141.55
5524	\$440.92	1,019,406	\$460.83	5524	1,735,837	\$ 239.66
5525	\$687.34	153,210	\$718.37	5525	21,309	\$ 348.84
				5526	5,670	\$ 669.59

The codes removed from CMS’s proposed 2017 Diagnostic Imaging APC Families are shown below, and are removed because they are not clinically similar in ACR’s judgment to Diagnostic Radiology. ACR asserts that Diagnostic Radiology and Diagnostic Imaging are not the same thing and that Diagnostic Imaging is a much broader concept that crosses multiple specialties. Until such time that a rationale and criteria based upon clinical similarity are made public so that the specialty societies may provide input to

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such decisions, ACR rejects these codes from its proposed Diagnostic Radiology structure.

List of Codes Removed from CMS' Proposed 2017 Diagnostic Imaging Families (Explanation for these judgments was provided earlier in this letter).

HCPCS/ CPT	2017P Short Descriptor	2017P APC	ACR Comment
91200	Liver elastography	5521	ask AIuM--specifies elastography wo imaging (I DOUBT Dx Rad)
93982	Aneurysm pressure sens study	5521	IR- move out of Dx Rad
43752	Nasal/orogastric w/tube plmt	5523	done by radiologists
93308	Tte f-up or lmtd	5523	Cardiology-move out of DX Rad
C9733	Non-ophthalmic fva	5523	Dx Angiography
36002	Pseudoaneurysm injection trt	5524	Endovascular US guided procedure IR
43756	Dx duod intub w/asp spec	5524	done by rads
47531	Injection for cholangiogram	5524	radiology, can use US or CT for guidance (IR)
93303	Echo transthoracic	5524	Cardiology-move out of DX Rad
93304	Echo transthoracic	5524	Cardiology-move out of DX Rad
93306	Tte w/doppler complete	5524	Cardiology-move out of DX Rad
93307	Tte w/o doppler complete	5524	Cardiology-move out of DX Rad
93350	Stress tte only	5524	Cardiology-move out of DX Rad
93351	Stress tte complete	5524	Cardiology-move out of DX Rad
93312	Echo transesophageal	5525	Cardiology-move out of DX Rad
93313	Echo transesophageal	5525	Cardiology-move out of DX Rad
93315	Echo transesophageal	5525	Cardiology-move out of DX Rad
93318	Echo transesophageal intraop	5525	Cardiology-move out of DX Rad
G0105	Colorectal scrn; hi risk ind	5525	Move out of Dx Rad-colonoscopy
G0121	Colon ca scrn not hi rsk ind	5525	Move out of Dx Rad-colonoscopy
75801	Lymph vessel x-ray arm/leg	5523	IR- move out of Dx Rad
C8923	2d tte w or w/o fol w/con,co	5572	Move out of Dx Rad
C8924	2d tte w or w/o fol w/con,fu	5572	Move out of Dx Rad
C8929	Tte w or wo fol wcon,doppler	5572	Move out of Dx Rad
C8921	Tte w or w/o fol w/cont, com	5573	Move out of Dx Rad
C8922	Tte w or w/o fol w/cont, f/u	5573	Move out of Dx Rad
C8925	2d tee w or w/o fol w/con,in	5573	Move out of Dx Rad
C8926	Tee w or w/o fol w/cont,cong	5573	Move out of Dx Rad
C8927	Tee w or w/o fol w/cont, mon	5573	Move out of Dx Rad
C8928	Tte w or w/o fol w/con,stres	5573	Move out of Dx Rad
C8930	Tte w or w/o contr, cont ecg	5573	Move out of Dx Rad
75563	Card mri w/stress img & dye	5593	Move out of Dx Rad
62303	Myelography lumbar injection	5525	Move out of Dx Rad

The codes below were moved up one level in the Proposed APC Structure to improve clinical and resource homogeneity based on ACR's expert judgment considering known resource use and to limit further erosion of capacity to deliver these services in community radiology settings.

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HCPCS/ CPT	2017P Short Descriptor	2017P APC	ACR Proposed APC
76010	X-ray nose to rectum	5521	5522
76498	Mri procedure	5521	5523
70557	Mri brain w/o dye	5523	5524
71270	Ct thorax w/o & w/dye	5571	5572
C8903	Mri w/cont, breast, uni	5571	5572
C8918	Mra w/cont, pelvis	5571	5572

The ACR suggests that CMS not implement its 2017 proposal until such time as the proposal has been completely and clearly explained, so that commenters can provide meaningful feedback and so that hospitals can have time to understand and prepare for the wide spread impacts associated with the proposed re-structuring. ACR suggests that CMS implement the ACR proposed Diagnostic Radiology APC Family structure and return the excluded codes to other clinically appropriate pre-existing APC families. ACR suggests that CMS return diagnostic cardiology procedures to a Diagnostic Cardiology APC Family and remove them from the Endovascular C-APC family where their clinical similarity has not been adequately explained. This is the preference of both Radiology and Cardiology Specialties.

Furthermore, ACR requests that CMS articulate how it will implement the legislative mandate to incorporate clinical similarity as a primary consideration in APC structure. The specialty societies and the hospitals need to have a clear understanding if long-standing principles of clinical similarity are being abandoned. Hospital business models rely upon their specialty departments for many aspects of their operations, and they will need time to transition if CMS is asserting a fundamentally different concept of similarity to that under which the hospital and physician communities currently operate.

Proposed Treatment of New and Revised CY 2016 Category I and III CPT Codes That Will Be Effective Jan. 1, 2016

In the 2015 proposed rule, CMS began the process of assigning new and revised Category I and III CPT Codes to APCs with status indicators for comment in the proposed rule cycle that are then considered final in the final rule and effective January 1 of the calendar year immediately to follow. The new and revised Category I and III CPT Codes are found in OPSS Addendum B and assigned the new comment indicator “NP” to indicate that it is a new or substantially revised code for the next calendar year (CY). For CY 2017 CMS is proposing to introduce an additional comment indicator “NC” to identify that the new or revised code has received a final APC assignment and status indicator in the final rule and that no further comments will be accepted. The ACR has

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reviewed the APC placement for its new single, revised and bundled radiology codes for 2017 and has the following comments.

- ACR recommends that the following add-on codes be considered for complexity adjustment within the comprehensive APC structure when billed with J1 codes on the same claim. 372X2- Trluml balo angiop addl art, 372X4- Trluml balo angiop addl vein, 369X7- Balo angiop ctr dialysis seg and 369X9- Dialysis circuit embolj.
- ACR recommends that 364X1- Prtl exchange transfuse nb be placed into APC 5182- Level 2 Vascular Procedures due to clinical similarity and resource intensity instead of its proposed APC placement of APC 5241-Level 1 Blood Product Exchange and Related Services.

Proposed Changes to Packaged Items and Services

CMS is proposing to change its packaging logic for status indicators Q1 and Q2 to make the decision to package or pay separately at the claim level rather than based on the date of service. CMS states in the proposed rule that this new packaging logic will result in a greater volume of conditionally packaged costs (and thus data) of items and services. However, CMS is entirely silent on how this policy is to be implemented. CMS typically provides claims accounting documents associated with the rule including the step-by-step order used to identify single claims used in rate setting. However, no explanation is included this year's documentation in order to determine how the rate setting logic is modified from last year. **See Technical Appendix.**

In the meantime, the ACR requests that CMS not move forward with this proposal for CY 2017 and instead provide the details needed for us to ensure that the packaging logic continues to capture as much data as possible for rate setting to keep hospital outpatient rates stable for those studies that include diagnostic, interventional, and therapeutic radiology. We would also expect CMS to correct errors in its implementation of the policy identified in the attached Technical Appendix.

Proposed Expansion of the C-APCs

The ACR has similar concerns about the aggressive expansion of C-APCs in such a short time period. The number of C-APCs has broadly expanded since they were first explained in 2014 and implemented in CY 2015. The result has been extensive packaging of many imaging procedures that appear on a claim with the "J" code. Because C-APCs package everything on the claim regardless of its relatedness to the primary service, the scope of radiology indirectly packaged is worth monitoring.

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This increased packaging tends to compress the extent to which packaged costs are captured in rates to the “average”. In general, this exerts negative pressure on rates. While the rates for surgical procedures as for other C-APCs initially may look like they increase, that impression is generally false, as the increased rate when an APC transitions from traditional to C-APC structure actually has to pay for more services (all those on the claim, regardless of date of service).

C-APC packaging will remove more and more claims volume from rate setting for the unpackaged radiology codes. The question arises as to whether the C-APC packaged claims are representative of all claims for separately paid procedures. If they are not representative, they can bias payment rates in the separately paid radiology space downwards or upwards. Determining representativeness is somewhat complex analytically across the broad spectrum of codes. However, where significant packaging is observed and where OPSS rates approach pressure on MPFS rates due to the DRA, it may become important to target analyses to determine whether any action can correct a negative ripple effect.

Table 1: Summary of Radiology Codes Billed Under Comprehensive APCs

Category	Number of Radiology Services	Dollars that are no longer separately payable under comprehensives
Total	2,147,515	\$ 1,298,178,144
Diagnostic Radiology	1,112,654	\$ 162,019,563
Interventional Radiology	838,035	\$ 1,061,421,207
Radiation Oncology	140,083	\$ 41,773,052
Nuclear Medicine	56,743	\$ 32,964,321

The ACR is concerned that consolidation of so many codes across specialties, technologies and clinical practice will have long-term effects on the departmental policies of hospitals, as revenue streams for outpatient services cannot be recognized as attributable to any particular department. Hospitals are overburdened by OPSS regulations, coding for quality measures, episode groups, APMs, etc. It is becoming increasingly difficult for hospitals to manage unanticipated outcomes. The ACR also believes that hospitals will see erosion of revenues and not be able to explain their source.

The ACR cautions CMS not to move too far too quickly potentially setting up the hospitals’ outpatient departments for unintended financial hardship. The ACR requests per the provided Technical Appendix that CMS provide as much detail as possible in the final rule on all of the proposed changes to the C-APCs, especially those that pertain to radiology and radiation oncology.

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SRS C-APC

Effective in 2016, CMS requires hospital coders to append a –CT modifier to all planning and preparation services related to a stereotactic radiosurgery (SRS) course of treatment for a patient. CMS suggests that in future years CMS will bundle all of these services and pay for all related services in one bundled payment that take place over one month. This could be related to codes on the same claim or on multiple claims. ACR has been working with other radiation oncology stakeholders on this issue and have found thus far that the components of radiation oncology coding are used for many types of radiation therapy patients and patients with cancer often have multiple treatments taking place at the same time for tumors found in one body area and then another, etc. Sometimes multiple techniques are used. Much of this activity appears as inconsistencies in the CMS data per our analysis. Therefore, it is hard to know if a planning, physics or simulation code is being reported for one treatment modality or another. If there are multiples billed in one-month's period of time and CMS makes only one bundled payment, there are services that could have been provided for a different course of treatment that won't be paid for. For example, our research found a significant number of claims that include both SRS and SBRT on the same claim, along with planning and preparation services that cannot be clearly associated with one or other procedure. The costs for the SBRT are then incorporated into the SRS claims because of their C-APC rules and SBRT is not paid for.

The ACR strongly believes that SRS was not a good course of treatment to use to test this concept of paying for related claims over one-month's period of time. CMS should have picked something that was more clean-cut with respect to related coding and capturing a full course of treatment in isolation. CMS should not implement this policy for SRS in the future and feels that more work needs to be done before this concept is used and spread further into other specialties' services.

The ACR urges CMS to continue to pay separately for the preparation and planning codes for SRS in the future. We are willing to work with CMS to clarify further the special nuances of SRS and other radiation oncology studies with regard to how they are not well suited to the C-APC expansion.

Proposal to Change the Beginning Eligibility Date for Device Pass-Through Payment Status

CMS is proposing to allow for quarterly expiration of pass-through status for devices, drugs, biologicals and radiopharmaceuticals to insure better data for placement of these new products into their final APC placement once the pass-through period has expired. For new devices, biologicals and drugs, payment may be made under the OPPTS temporarily via the use of transitional pass-through payments for at least two but no more than three years. The pass-through period for new drugs and devices begins in the quarter

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that the application is approved by CMS. Therefore, drugs and devices with pass-through status beginning in the first quarter of the year would receive the full three years of eligibility in the regulatory cycle; those that went into effect in the third quarter would be priced on two and a half years-worth of data. With the new proposal, allowing the pass-through period to expire quarterly would allow for a period of time closer to the statutory limit of 3 years for each item on pass-through status. In addition, CMS is proposing to calculate the cost of device-intensive procedure payments at the HCPCS code level instead of at the APC level in order to ensure that device-intensive status is properly assigned to all device-intensive procedures. CMS estimates pass-through totals to equal approximately 0.24% of the total OPPI spending.

The ACR has made several requests in the past that CMS keep new drugs in pass-through status for the full 3 years in order to maximize the collection of cost data and the ultimate correct placement of these codes in APCs to produce the most accurate payment. What CMS proposes for CY 2017 appears to accomplish this goal.

The ACR is in support of CMS moving forward and finalizing this proposal.

Site Neutral Payments

CMS is proposing to make site neutral payments to new off-campus sites that provide items and services to outpatients based on the Medicare Physician Fee Schedule (MPFS) technical component rate and would deny their eligibility for payment under HOPPS. This proposal stems from Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) which requires that certain items and services furnished by certain off-campus sites shall not be considered covered outpatient department services for purposes of OPPI payment and shall instead be paid “under the applicable payment system” beginning January 1, 2017.

CMS proposes that hospitals will be required to report any new services that are provided in provider-based departments (PBDs) which would then need to be billed differently at the Medicare Physician Fee Schedule (MPFS) rate. CMS does not have sufficient time before January 1, 2017 to develop a mechanism for off-campus PBDs to bill for non-excepted items and services under a payment system other than the OPPI (*i.e.*, PFS) because it would require significant changes to enrollment forms, claim forms, hospital cost reports, etc. Therefore, CMS proposes a temporary solution for one year (CY 2017) where payment will be made to a billing physician or non-physician practitioner (NPP) under the PFS at the non-facility rate. CMS does not believe that under current systems, off-campus PBDs can be paid for its facility services under the PFS, but it is exploring options for CY 2018. Alternatively, if an off-campus PBD wishes to bill Medicare for those services, it could enroll as another provider type (ASC or physician group practice).

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The ACR believes that several of the proposed provisions limiting the exception to Section 603 regarding the “Applicability of Exception at Section 1833(t)(21)(B)(ii) of the Act” go well beyond Congressional intent. Many of the added provisions are overly burdensome to hospital-owned facilities and will impose severe consequences.

For example, CMS proposes to prohibit an off-campus OPD that was billing Medicare at the time of enactment of PL 114-74 from either moving or expanding into new “clinical family” of services. If CMS restricts these entities to their current address, they do not have the freedom of movement that tenants deserve. More importantly, they lose any negotiating power they may have had with their landlord when it comes to the rent being charged for the space they occupy. Cornering sites into staying in a specific leased space causes reduced quality of care for patients as they now are coming to a facility where the landlord no longer wants to make upgrades to the building that may be needed. The tenants are also then left with no choice but to pay the level of rent that is dictated and not necessarily fair market value.

Also is it very burdensome for existing sites to keep track of services provided to Medicare patients, to determine which ones are not grandfathered, and to process these payments under two separate payment systems. This policy seems unfair and a logistical challenge. This may cause patients to travel to a different location to obtain a service that could have been made available at an existing off-campus OPD.

We believe that prohibiting PBDs that existed at the time of enactment of PL 114-74 from moving or adding new services is contrary to the clear and unambiguous meaning and intent of the statute.

The statutory language is quite clear in terms of the application of the exception. It states:

For purposes of paragraph (1)(B)(v) and this paragraph, the term “off-campus outpatient department of a provider” shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.

The ACR requests that CMS not expand the site neutral policy beyond the original intent of Section 603. However, if CMS does move forward, we request that imaging centers be completely exempt from the site neutral policy. Imaging studies have been through multiple rounds of cuts since 2006 to the technical component in the Medicare Physician Fee Schedule (MPFS) causing many radiology offices to close because they cannot cover their costs. If hospitals are held to a similar payment schedule, they will no longer be able to cover their costs either possibly causing closures as well.

Changes for Payment for Film X-Ray

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The Consolidated Appropriations Act mandates that, effective for services furnished during 2017, payment under the OPSS for imaging services that are X-rays taken using film shall be reduced by 20 percent. This is an incentive for hospitals to stop using outdated X-ray equipment and to make the transition over to digital technology. CMS is proposing the use of a new modifier by hospitals for film-based X-ray services billed to Medicare for payment. Effective January 1, the use of this proposed modifier would result in a 20 percent payment reduction for the film-based X-ray services. CMS states that they will make proposals on the reduction of imaging services for X-rays taken using computed radiography technology in future rulemaking.

The ACR seeks clarification on the proposal to develop a –XX Modifier. It is unclear from the rule whether –XX is the proposed modifier or if this is a placeholder for the modifier under development.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access of Medicare Act of 2014 directs the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services through clinical decision support mechanisms (CDSMs). This new program is due to be implemented for all outpatient settings including the office, hospital outpatient and ambulatory surgery centers. Ordering practitioners will be required to consult AUC at the time of ordering advanced diagnostic imaging, and imaging suppliers will be required to report information related to such consultations on claims for all applicable advanced diagnostic imaging services paid under the MPFS, the OPSS, and the ASC payment systems.

The CY 2017MPFS proposed rule includes proposed requirements and processes for the second component of the Medicare AUC program, which is the specification of qualified clinical decision support mechanisms (CDSMs), the electronic tool through which the ordering practitioners consult AUC. It also proposes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements.

The ACR comments extensively on this issue in our comments on the Medicare Physician Fee Schedule proposed rule. Below we list our major requests:

- ***We ask CMS to give adequate advance notice to the public and clarify in the final rule that furnishing professionals (FPs) will start reporting AUC information beginning January 1, 2018.***
- ***Since Section 1834(q)(3)(C) of the statute requires that CMS publish an initial list of mechanisms by April 1, 2016, and that deadline was not possible due to the timing of the rulemaking cycles, the ACR requests that CMS publish the list of qualified mechanisms by April 1, 2017.***

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- *We ask the Agency to finalize the proposed requirement that all orders for ADIS should include a unique consultation identifier to indicate that consultation with CDS took place. Additionally, imaging that is not done or changed to a non-advanced diagnostic imaging examination such as ultrasound as a result of AUC consultation should be tracked via registries just as imaging that is done is tracked*
- *The ACR urges CMS to implement this program in as comprehensive a way as possible including all clinical conditions. It is difficult to implement a partial CDS program and then to know when it is required to expand it further. Simplicity is better met in this case to be as inclusive as possible..*

EHR Provisions

CMS proposes to reduce the reporting period in CY 2016 from the full calendar year to any 90 consecutive days within the year for those who have participated in previous years of the program. CMS also proposes to reduce the CQM reporting period to 90 days to coincide with the reduced EHR reporting period.

The ACR is in support of these proposals.

Summary of Recommendations

ACR supports the following proposed policies:

- The removal of the nuclear medicine and interventional radiology codes from the radiology imaging APCs.
- A reduction in the EHR reporting period and corresponding CQM timeframe to 90 consecutive days.
- The quarterly expiration of pass-through status for devices, drugs, biologicals and radiopharmaceuticals

ACR objects to moving forward with the following proposed policies and suggests alternative action:

- Do not implement the 2017 proposed re-structure of APCs, delay action while continuing the 2016 structure for 2017 unless specific exceptions are necessary.
- Implement the Proposed Alternative Diagnostic Radiology APC Structure described in this letter and shown in Appendix >>>.
- Explain the intent of the 2017 proposals, including clarifying how the restructuring will adhere to the statutory intent that clinical similarity play a primary role in APC structures. Clarify to the specialty societies and hospitals the

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criteria that will be used for clinical similarity and explain how each change to the APC structure is consistent with those criteria.

- Provide explanation for exceptions to the 2 times rule that affect diagnostic radiology
- Do not implement new claim-level packaging policy without providing details required for understanding how this will be implemented.
- Provide further detail on the proposed C-APC expansion
- Continue to pay for SRS preparation and planning codes separately
- Do not expand the site neutral policy beyond the original intent of Section 603 of the BBA.
- Explain how APC restructuring will be evaluated in terms of year-to-year fluctuations in rates +/- 10%. How will CMS policies ensure stable and predictable payment levels? What time frame will be provided for hospitals to adapt to significant changes?
- Provide clarification on details of the modifier for film X-Ray.
- Correct APC assignments that do not make clinical sense.
- Continue APC placement of G0296 and G0297 in their CY 2016 Level II APC assignments of 5582 and 5570 respectively.
- Provide the documentation requested in the Technical Appendix to this letter.

Thank you for the opportunity to comment on the Proposed Rule. 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 Dominick Parris at 800-227-5463 ext. 5652 or via email at djparris@acr.org.

Respectfully Submitted,

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Memorandum (August 26, 2016)

To: Pam Kassing, ACR
From: Rachel Feldman & Team, The Moran Company
Subject: Technical Appendix to ACR Comment Letter

Technical Appendix

Drafted by The Moran Company Based on Analytic Work Commissioned by ACR

The function of this technical appendix is to clearly delineate why ACR is asking for increased transparency and detailed explanation in the 2017 Final OPSS rule. CMS is generally aware that The Moran Company is one of a few analytic firms that makes every effort to replicate the OPSS rate setting process utilizing the rate setting files, claims accounting documents, and various addenda and related materials released with the proposed and final rules. The Moran Company has generally been able to replicate the CMS geometric means and single claims frequencies with a high rate of precision. This year, even a close replication was very difficult, due to a decrease in the amount of information, and gaps in information provided by CMS in these sources.

We would appreciate clarifications and answers to questions detailed below in the final rule.

APC Revised Structure

The Moran Company prepared a comparison table showing all codes by APC/C-APC for the 2016 and 2017 proposed structures. In reviewing diagnostic radiology, and interventional radiology codes as well as the endovascular APC structure, we realized that a relatively major restructuring had been done across the entire OPSS system, with no discussion of the reasons or direction of this restructuring in the rule except CMS's references to changes being made to the diagnostic radiology APC structure. Comparing the ACR proposed APC structure discussed with CMS in the spring to the 2017 proposed structure, we identified major differences that we found inconsistent with our presentation to CMS and were unable to understand the intent. Further examination of the range of changes revealed the elimination of a number of APC families and their collapse into clinically different, and perhaps, loosely related families.

When specialty societies and others with overlapping interests review OPSS rules to look at their codes of interest, it is not immediately apparent that APC structures have changed. In most years before the 2016 restructure proposal, which was explained to some degree, CMS has provided an

explanation in the proposed and final rules for any changes it makes to the APCs. Those explanations are very important to commenters because it allows them to understand both the immediate change and the logic driving CMS to make future changes. We would ask that CMS resume provision of this level of information in each proposed and final rule, and provide some explanation regarding its intentions. While we understand the intent to expand packaging in the OPPTS at a general level as discussed in the proposed rule, the actual approach to specific APC changes can have a variety of impacts, including some that are probably unintended.

In this 2017 proposed rule, the restructuring effort creates a great deal of volatility from one year to another, shifting weights up and down across the spectrum of the OPPTS. Large increases and decreases to rates resulting strictly from re-organizing APCs create uncertainty and a wide range of concerns for hospitals, their specialty departments, and to others involved with the delivery of outpatient hospital radiology services. Rate stability and predictability are a concern for the ACR, as the radiology departments in hospitals must plan for the staffing and equipment to deliver an expected volume of services, adapt their budgets and staffing, negotiate for space and plan technology upgrades, maintenance, and replacement, in a multi-departmental financial structure. Introducing uncertainty into hospital outpatient departments can disrupt financial planning, and create a variety of internal political and operational problems.

Medicare fee-for-service is a relatively modest part of outpatient operations and revenues in many hospitals, and the hospitals may not be tracking the specific sources of volatility in their revenue streams. Many are likely to experience this volatility in gradual erosion in revenues which they find difficult to trace: in some cases the revenues may shift from radiology to surgery, or from cardiology to radiology (both of these shifts are likely due to 2017 proposed changes), but this will not be obvious to the hospitals until it happens. If these sequelae are within the scope of outcomes CMS expects, then it would be best to explain them to the hospitals by disclosing the reasons in the regulations. Such disclosure enables hospitals and specialty departments to voice their concerns, or to prepare to adapt their operations and decision making to align with expected changes. Without such transparency, most hospitals will remain in the dark, gradually experiencing revenue shifts they were not expecting and cannot easily explain. This confusion does not serve any policy objective and should be avoided. Because ACR represents a large number of hospital based members and coordinates with other specialty societies as well as hospital based radiology administrators, we invest more in the technical expertise needed to identify the often inadvertent consequences that flow from technical changes in the OPPTS.

We would ask that you provide answers to the following questions in some detail in the final rule, and in future proposed and final rules:

- Were any APC families added or deleted? Which ones and why?
- Were the codes from deleted APC families moved to other APCs? Please provide code by code changes listed.
- Please explain the basis for blending groups of codes historically treated as clinically different, into the new blended structure?

- Please identify any APCs that have been converted to C-APCs.
- If there are elements of C-APC policy are affected by conversion of a traditional APC to a C-APC, please make those explicit. For example, add-on codes that are packaged in traditional APCs may be allowed to trigger complexity adjustments in C-APCs. In the ACR's new code recommendations, the ACR asked that certain add-on codes that reflect significant cost intensity be treated as complexity adjusting add-on codes. We have not received any response to this request in this proposed rule.

We note that CMS made major changes in 2015, 2016, and proposals for 2017. The original comprehensive APC methodology was announced in 2014 with an explicit delay of implementation to 2015 at CMS's initiative. This delay allowed interested parties to think about the impact of this level of packaging. It also allowed CMS to conduct more analysis in response to comments to refine the policy in 2015. No such notice or adjustment period has been offered for the major restructuring in 2016 or 2017. Many interested parties, including ACR will ask that CMS delay the 2017 re-structuring, NOT to stop movement, but to provide time for CMS to explain its intentions and direction, so that commenters can make meaningful comments and identify issues that could lead to unintended consequences if not considered. A delay of one year would also allow CMS to consider the positions of specialty societies and the needs hospitals have to adapt their departmental business structures to any ultimate decisions CMS makes to blend APCs crossing major specialty lines.

Conditional Packaging at the Claim Level and other Methodology

CMS announces its intent to package conditionally packaged procedures identified by status indicators of Q1 and Q2 at the claim level, instead of the date level. ACR has a vast number of codes that have been designated as conditionally packaged, and we periodically evaluate the effects of this packaging on radiology departments in hospitals. We asked our consultants to model the impact of this proposed packaging policy and they found that there was no specific information in the proposed rule explaining how the new policy was to be implemented. When conditional packaging was initially introduced, it was in response to an ACR impact analysis that showed that policy packaging many of the codes that are currently conditionally packaged resulted in a loss of about \$900 million from OPSS rate setting. CMS very appropriately created a solution with the introduction of conditional packaging that allowed the return of those dollars to rate setting, implemented the intent of packaging ancillary procedures, but also recognized that a great many claims included conditionally packaged procedures without other major procedures. Conditional packaging, then, allowed for separate payment for those cases where other major procedures were not present on the claim.

With the proposed methodological change to package conditionally packaged codes at the claim level, ACR is concerned that it be able to evaluate the policy. Without greater detail either in the body of the rule, or in the claims accounting documents specifying the rules for claim level packaging, this is difficult. The Moran Company has been submitting questions to CMS and has received answers to these questions, though it has taken some time, and recent answers do not

allow time for further analytic modeling before comments are due. We very much appreciate CMS providing answers to detailed questions. We would ask that the substance of these questions be addressed in the appropriate parts of the Final rule, and that specific detail be provided when future methodological changes are made. The Moran Company found, for example, that CMS is packaging Q2 procedures with procedures that have other Status Indicators than “T”. Based on CMS answers to Moran Company Questions, we understand that this was not supposed to occur and will be corrected in the final rule. This is an example of how interested parties such as ACR can utilize our technical resources to partner with CMS to generate meaningful comments and questions that advance our mutual interests. This cannot happen without greater transparency and more specific information about how new policies or policy directions are going to be implemented.

CMS also has been creating new Addenda and downloadable data documents which have the potential to be very useful, but are not very well documented. We ask that CMS add to each rule, a section that identifies the documentation available for download, and provides more detailed specifications for each data source. The Moran Company submitted questions to CMS to better understand the difference between similar columns of data in the cost statistics file and Addenda J, for example. While CMS provided answers to these questions, these data were needed to evaluate policies early in the rule cycle and this information would have been more valuable if it had been explained in the rule or in the related data sources.

We appreciate your attention to improving the specificity and completeness of the documentation in the rule and associated data sources. Over the years, the OPPS has become increasingly complicated, with many interacting policies and implementing methodologies. CMS could contribute greatly to the public’s understanding of this payment system by expanding and updating its documentation consistent with the Administration’s objective of transparency.