

September 14, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2008
Payment Rates; Proposed Rule**

Dear Mr. Weems:

The American College of Radiology (ACR), representing 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists, appreciates this opportunity to comment on the proposed notice “Hospital Outpatient Prospective Payment System (HOPPS)” published in the *Federal Register* on August 2, 2007. The ACR would like to present positions on the following issues: the complex proposal by the Centers for Medicare and Medicaid Services (CMS) to package payment for seven categories of supportive ancillary services, low dose brachytherapy (LDR), cardiac computed tomography (CT) and coronary computed tomographic angiography (CTA), and the implications of the proposed rule with respect to the caps on imaging payments imposed by the Deficit Reduction Act (DRA).

Packaging of Drugs and Imaging Services

CMS is proposing to package seven categories of supportive ancillary services into the primary diagnostic or treatment procedure(s) with which they are performed. Included in these seven categories are five categories of critical importance to radiology: imaging guidance services, image processing services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals and contrast media, and radiation oncology services.

In general, the ACR opposes packaging of any of the drugs and imaging-related and radiation oncology services. The proposed rule provided insufficient information for stakeholders to assess the reasonableness of the proposed packaging. For example, no information was provided regarding the Ambulatory Payment Classifications (APCs) to which the various ancillary services would be packaged, and no information was provided regarding the impact of packaging by category of ancillary services, only aggregate impacts of the packaging proposal were provided. However, aggregate impacts make it impossible for stakeholders to determine how each service category will be affected.

Further, we believe that CMS needs to describe in much more detail how it has determined payment levels for ancillary services with a “Q” status indicator. As indicated in the technical appendix to these comments, prepared with the assistance of The Moran Company, we believe that CMS has used too few claims to determine these payment levels and that the resulting

payment amounts are artificially depressed. In addition, CMS has not explicitly indicated how payment would be made when several services with a “Q” status indicator are provided in the same session, especially in cases where no other separately payable service has been provided. ***The ACR believes that the likely underpayment of ancillary services with a “Q” status indicator (when these services are provided alone or together with other “Q” services) is sufficient grounds for delaying the proposed packaging of ancillary services until stakeholders can be assured that this matter has been adequately addressed.***

The comments that follow provide our more detailed assessment of the implications of the proposed packaging on individual categories of ancillary services of concern to the ACR and its members.

1) Guidance Services

CMS is proposing to bundle 31 guidance procedures, including 26 radiology guidance codes, the placement of the breast clip code and 2 radiation oncology codes (port films and stereoscopic x-ray). It is the ACR’s understanding that CMS wants to package services that are always or commonly performed together. The ACR is opposed to the diagnostic imaging guidance services being bundled because none of the imaging guidance codes are commonly done with any one or only a few surgical or procedural codes, significantly raising the risk that these services will be underpaid if packaged. The reason that the Current Procedural Terminology (CPT®) Editorial Panel built different guidance codes is because they represent different modalities and thus different costs and cognitive approaches (i.e., CT-guided vs. ultrasound-guided). The ACR is concerned that if CMS packages these codes that hospitals will begin to encourage physicians to use the lower cost modality without taking into consideration the differences in clinical utility and outcomes. The APC Advisory Panel has twice recommended that imaging guidance be paid separately from the procedural codes. The ACR believes that this recommendation is the right one and urges CMS to maintain this position.

The ACR requests a delay in implementation of this proposal until CMS can provide enough information to show the impact of payment and distribution of costs. This type of information should be revealed in the notice of proposed rule making giving specialties sufficient time to comment.

2) Image Processing Services

CMS is proposing to package 11 image processing services. This package group includes: Doppler echo (93325) into echo transthoracic (93350) and cardio stress (93017), 3-D processing codes (76376, 76377), cine (76125), special x-ray contrast (76350), Computer-Aided Detection (CAD) breast MRI (0159T) and CAD chest (0174T, 0175T). The ACR is opposed to CMS packaging image processing services. The 3-D processing codes were recently revised by the CPT Editorial Panel to show that these services are not typically a part of CT or (Magnetic Resonance) MR services. When a 3-D reconstruction is typically part of a CT or MR study, these studies are usually clinically recognized as CTA or (Magnetic Resonance Angiography) MRA services. When 3-D reconstructions are requested from CT images, it is usually for the purpose of evaluating bone fractures before a treatment decision is made, reconstruction of hips before orthopedic surgery or

reconstruction of sensitive brain vessels in preparation for neurosurgical planning for treatment of craniosynostosis. These do not represent quick

3-D reviews of CT or MR images but careful and time-consuming reconstructions taking anywhere from 20 to 45 minutes to help in the treatment of patients. There are facilities such as Massachusetts General Hospital that have special 3-D staff, workstations and facility space devoted to providing these services. The ACR is concerned that hospitals will not place importance on the value of these services and continue to support their availability to other specialists in the hospital if they are being inadequately reimbursed by Medicare.

In addition, the ACR is opposed to the packaging of the CAD services with breast Magnetic Resonance Imaging (MRI) and chest because they are currently not typically done with the primary services. These services are currently coded using Category III CPT codes (temporary codes for emerging technology, services and procedures). Further data needs to be collected on the frequency and coding patterns of billing CAD with chest and MRI of the breast, before a decision can be made that the practice is typical.

The ACR requests that CMS provide data showing how often codes proposed for packaging are billed together with other services (and which other services are involved) so that specialty societies can be in a better position to determine the reasonableness of the proposed packaging. In the meantime, the ACR requests a delay of this packaging until this information is made publicly available.

3) Imaging Supervision and Interpretation

There are 33 interventional codes where the status indicator was changed to an "N" for 2008 and 93 codes that were assigned a "Q" status indicator. CMS proposes to assign status indicator "N" to those Healthcare Common Procedure Coding System (HCPCS) codes that are believed to be always integral to the performance of the primary modality and to package their costs into the costs of the separately paid primary services with which they are billed. CMS also proposes to assign a status indicator "Q" to those HCPCS codes that are believed to be typically integral to the performance of the primary modality, and to package payment for their costs into the costs of the separately paid primary services with which they are usually billed, but to pay those HCPCS codes separately in those cases in which no other separately paid primary service is furnished in the hospital outpatient encounter. The ACR feels that these changes are too far reaching to be accomplished in a single regulatory cycle.

The following coding scheme represents a common interventional procedure. The packaging, as proposed by CMS, shows a severe cut in reimbursement to hospitals. Note that the "T" code status further reduces the bundled payment by another \$1,467.12.

<u>EVALUATION AND PERCUTANEOUS REVASCLARIZATION OF GRAFT</u>				
Code	Description	*SI 2008	2007 Payment	2008 Payment
36145x2	Artery to vein shunt	N		
75790	Visualize A-V shunt	Q	\$584.32	
G0393	AV fistula or graft venous	T	\$2,639.19	\$2,934.24
75978x2	Repair venous blockage	Q	\$767.90	
35476	Repair venous blockage	T	\$1,319.60	\$1,467.12
	Total		\$5,311.01	\$4,401.36

*SI = Status Indicators – N= payment is packaged into APC rates; Q= packaged services subject to separate payment; S= significant procedure, not discounted when multiple reduction applies (separate APC payment); T= significant procedure, multiple reduction applies (separate APC payment); V= clinic or emergency department visit (separate APC payment); X= ancillary services (separate APC payment).

Another example of the potential impact of the proposal relates to interventional radiology procedures such as a cerebral arteriogram that only involve selective catheterizations and supervision and interpretation codes. Under the CMS proposal, codes assigned a “Q” status may occasionally be provided at the same time and at the same hospital with one or more other procedures for which payment is currently packaged under the OPPS, most commonly injection procedures. In these cases, CMS would not treat the imaging supervision and interpretation services as dependent services for purposes of payment. An example is shown below.

<u>CEREBRAL ARTERIOGRAM</u>				
Code	Description	SI 2008	2007 Payment	*2008 Payment
36217	Place catheter in artery	N		
36216x2	Place catheter in artery	N		
36218	Place catheter in artery	N		
75671	Artery x-rays, head & neck	Q	\$1,279.92	?
75680	Artery x-rays, neck	Q	\$1,279.92	?
75685x2	Artery x-rays, spine	Q	\$2,559.84	?
	Total		\$5,119.68	?

*2008 Payment rate for the "Q" codes is \$721.14.

We have two concerns. The first is the dramatic reduction in payment for the Q codes for 2008. The second is that if any other procedure codes with status "S," "T," "V," or "X," are included on the same claim there would be no payment for 75671 whatsoever. Because patients commonly receive multiple services in hospital outpatient departments, it appears the CMS proposal would essentially eliminate payments for arteriograms in many circumstances.

The ACR recently asked The Moran Company to run aggregate impact data on the effects of the various packaging proposals. For interventional radiology it is estimated that hospitals could see a 25% reduction in reimbursement in aggregate as a result of this packaging. Also, as discussed in the technical appendix, The Moran Company's discussions with CMS and analysis shows that the methodology throws out many multiple claim records that could be used to value these imaging codes. The resulting average costs are much lower than otherwise would be calculated with the higher number of claims.

The ACR strongly feels that packaging such a major portion of this modality of radiology could have negative implications for hospitals that provide interventional radiology services and possibly cause access problems for patients. The ACR supports the APC Advisory Panel's recent recommendation to delay implementation of packaging of the supervision and interpretation (S&I) codes for 2008.

CT of Lumbar Spine and Myelography

Within the packaging section of the S&I, CMS proposes to bundle the injection procedures (61055 or 62284) and S&I for a myelogram (72265) into CT of the spine (72132).

The ACR is strongly opposed to myelograms being packaged with CT of the lumbar spine. This is an example of how CMS efforts to begin simple packaging is farther reaching into a more complex level providing no data or understanding of why CMS feels this is necessary or warranted. ***The ACR requests that CMS not package myelograms with any other radiology procedures. The ACR also would like to see frequency data which raises concern by CMS to want to package these studies.*** A myelogram is a separate diagnostic study that can stand alone and can provide very different and independent clinical information from that provided by CT of the lumbar spine. Myelography is clearly not ancillary to the performance of lumbar spine CT.

4) Diagnostic Radiopharmaceuticals

CMS plans to bundle 47 specific HCPCS codes that are radiopharmaceuticals. Radiopharmaceuticals are drugs (and not supplies as CMS appears to imply in the proposed rule) and they should be reimbursed separately in the facility setting to the same extent as other drugs.

The ACR also believes that packaging all diagnostic radiopharmaceuticals into diagnostic nuclear medicine studies is too radical a change to make in one regulatory cycle. CMS has not provided sufficient time or crosswalk information for specialties to adequately review the matching of the drugs with the procedures and the implications of the proposed packaging. The ACR is very concerned that the proposed reimbursement methodology will create an incentive for hospitals to shift away from advanced technologies, which in turn will have negative implications for the quality of patient care.

The ACR believes that CMS should continue to pay separately for radiopharmaceuticals above any new calculated and proposed threshold that is adopted in the final rule consistent with what is done for other drugs. The ACR is concerned that if pricing of radiopharmaceuticals is not adequate, then hospitals will put undue pressure on physicians to use less expensive radiopharmaceuticals for nuclear medicine procedures even when that might not be the most clinically appropriate selection for the patient. *The ACR would like to work with CMS further to review data to insure that all radiopharmaceuticals are being paid adequately in the hospital outpatient setting.*

Therapeutic Radiopharmaceuticals

The ACR appreciates CMS' decision to continue to pay separately for therapeutic radiopharmaceuticals. However, there are some therapeutic radiopharmaceuticals that are under priced. For example, Yttrium-90 (i.e., Zevalin) has an acquisition cost of \$24,000 and payment rate of \$12,000. HOPPS payment rates for products involving monoclonal antibodies could prevent the growth of and access to molecular imaging under nuclear medicine because hospitals may choose not to continue offering the service at a loss and manufacturers may then choose to no longer produce the products or develop new ones.

Again, the ACR would like to work with CMS further to review data to insure that all radiopharmaceuticals are being paid adequately in the hospital outpatient setting.

5) Contrast Media

The ACR believes there is insufficient justification for treating contrast media agents differently from other injectable drugs administered in the hospital outpatient setting. Contrast media agents are drugs that are handled through the pharmacy and they should be treated in the same fashion as all other drugs, and not subject to unique packaging rules.

The ACR recommends that CMS delay implementation of the packaging of contrast media until more information has been provided to stakeholders about where these drugs are being packaged and about the potential impact of such packaging on payments for contrast media agents. Payment policy for contrast media should be consistent with how CMS pays for all other drugs under OPSS.

Uterine Fibroid Embolization (UFE)

The ACR is supportive of the APC Advisory Panel's consideration and recommendation regarding the assignment of CPT code 37210, Uterine Fibroid Embolization (UFE), to APC 0229. The ACR believes that APC 0229 contains vascular procedures that are similar to UFE and utilize like-resources and urges CMS to finalize 37210 to APC 0229.

Low Dose Rate Brachytherapy (LDR)

CMS has created a composite APC or encounter-based group for low-dose rate brachytherapy, where multiple claims for 55875 (placement for needles or catheters) and 77778 (interstitial treatment of prostate) are used to make single claims thereby incorporating more hospital cost data in determining the payment rate. This changes the payment rate for the services from \$3,298.29 in 2007 to \$3,127.35 in 2008. The ACR supports this composite APC methodology.

The ACR asks that CMS delay implementation of the placement of the T status indicators on radiation oncology codes until there is disclosure as to which codes this policy decision affects. It is not clear which codes would result in economies when billed with 55875 and 77778. The ACR believes that specialty societies have a right to the open review of the codes that are affected during the notice of proposed rule making process with comment period.

Placement for Cardiac CT and Coronary CTA

The ACR appreciates CMS' proposal for the placement of cardiac CT and coronary CTA in new APCs with a slight increase in payment. The ACR had testified to the APC Advisory Panel in March 2007 urging the Panel to consider how new technologies should be assigned to APCs.

The ACR is still concerned with how new technologies are being handled under OPSS. There has not been consistency of 1) when they are assigned to new technology APCs; 2) how long they remain in new technology APCs; and 3) when they are assigned to regular APCs. The ACR requests improvement in the placement of consistency of how new technologies are handled under OPSS. These services are the cutting edge advances in medicine that need to be available for future patient care.


Implications for DRA-Mandated Caps on Imaging Payments

The ACR is concerned that CMS has not fully considered the policy implications of the packaging proposal as it relates to the application of the Deficit Reduction Act where payment for imaging services is based on the lower of the payments under OPSS or the technical component under the physician fee schedule. Given the current interaction between the two payment systems, we believe that the impact of proposed OPSS policy changes on Medicare physician payments should be clearly stated by CMS in order to provide the public with all the information needed to provide fully informed comments on the proposed OPSS rule. In our opinion, failure to do this creates an inappropriate environment of uncertainty for providers as well as Medicare contractors. We urge CMS to correct this deficiency in the final rule.

Conclusion

Thank you for the opportunity to comment on this proposed rule. The ACR looks forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Sneha Soni at (800) 227-5463, ext. 4576 or via email at ssoni@acr.org.

Respectfully Submitted,



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TECHNICAL APPENDIX

Likely Underpayment of Services with a “Q” Status Indicator

In the FY 2008 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule, CMS proposed making far greater use of Status Indicator “Q” for conditional packaging.

The Q status indicator means that the HCPCS code is conditionally packaged in one of three basic ways:

- 1) The code is only packaged with a specific other code, such as direct observation services (G0379 if billed with G0378),
- 2) The code is part of a composite APC, or
- 3) The code can be paid separately if it appears without another major procedure or packaged if it appears with another procedure.

Most of the codes with Q status indicators fall into item number 3.

In the proposed rule, CMS provides the following general logic for how to handle a HCPCS code with a Q status indicator:

- 1) If the HCPCS procedure code is performed on a day without any other HCPCS codes that are major procedures (status indicators S, T, V, X), then the HCPCS code is made (or “promoted”) to a major procedure.
- 2) If there are any codes with S, T, V, X, performed on the same day, then the HCPCS code is assigned an N status indicator (packaged).

CMS does this assignment prior to any application of the single/multiple procedure claim methodology, and as a result does not use many single claims as they are potentially could. If the assignment of a new status indicator for the HCPCS code with Q status indicator was made during the single/multiple methodology, it is possible to create pseudo-singles out of lines that are otherwise not used in rate-setting.

Examples of limitations of the CMS policy are noted below:

Interaction of multiple bypass codes and when CMS assigns the new status indicator. CMS views bypass codes as a major procedure, therefore if a HCPCS code with status indicator Q appears on the same day as one or more bypass codes, it is converted to packaged (status indicator N). However, if there are two bypass codes also on the claim, the HCPCS code with the status indicator Q will not be used. Because there are two bypass codes, they are each pulled out as a major procedure (without any packaging), leaving just the code with the Q indicator status left at the end because CMS made the assignment of an N status indicator to this code at the very beginning prior to consideration of the bypass list. Had CMS made the assignment during the single/multiple process, after the bypass lines were pulled out, the HCPCS code with status indicator Q would be left, which then gets promoted to a “major” (instead of SI=N) and used to set the payment rate for this code rather than not being used at all.

Interaction of bypass code with multiple units and when CMS assigns the new status indicator. CMS views bypass codes as major procedures, even if they have multiple units. Following the CMS methodology, the code with status indicator Q would change to a status indicator N on a claim with a bypass with multiple units. However, bypass codes with multiple units do not have packaging included on them, and therefore the HCPCS code with the status indicator Q originally does not get used at all. If instead CMS assigned the new status indicator during the single/multiple process, CMS would pull out the bypass code, then convert the status indicator Q to a major procedure, and create a pseudo-single claim from the HCPCS with the status indicator Q.

Multiple Q status indicators. CMS did not expect multiple codes with status indicator Q on a claim. As a result, neither of them are captured as pseudo-single claims. Example: A claim which has two HCPCS with status indicator Q and nothing else. CMS' assignment before the single/multiple process makes these two have status indicator N, then the claim is viewed as a multiple minor and not used. If instead, each had been promoted to a major, then a pseudo-single claim for each code could have been created since there are two majors with no packaging and so split apart. This would have led to two additional pseudo-single claims as opposed to the codes not being used at all.

All of the above may explain why proposed 2008 payments for services with a "Q" status indicator appear to be significantly lower than those in 2007, as shown in the following table. As noted, interventional radiology would be the category most negatively affected.

"Q" Status Indicator Procedures Represent Uncertain Estimates **

Codes with "Q" Status Indicators in 2008**	Estimated Payments 2007 Method 2008 Conversion Factor	Estimated Payments 2008 Method, 2008 Conversion Factor	Change \$
General Radiology	\$ 41,001,066	\$ 19,509,562	\$ (21,491,503)
Breast (no "Q"s)			
Ultrasound	\$ 52,695	\$ 46,894	(5,801)
CT	9415741.545	\$ 8,180,667	\$ (1,235,075)
PET			
PET/CT			
Interventional Radiology	\$ 479,100,566	\$ 291,170,204	\$ (187,930,363)
MR			
MRA			
Nuclear Medicine			
Radiation Oncology	\$ 12,410,438	\$ 5,391,928	\$ (7,018,510)
Guidance			
Total Radiology	\$ 541,980,506	\$ 324,299,255	\$ (217,681,251)