



August 29, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements

Dear Administrator Berwick:

The American College of Radiology (ACR), representing more than 34,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, appreciates this opportunity to submit comments on the proposed changes to the 2012 Hospital Outpatient Prospective Payment System (HOPPS) published on July 18, 2011. The ACR will provide comments on the following topics:

- Computed Tomography of the Abdomen and Pelvis
- Endovascular Revascularization of the Lower Extremity
- Payment Reductions that are secondary to new “bundled” CPT codes
- Reassignment of CPT code 78075 *Adrenal imaging, cortex and/or medulla* 29 percent reduction in payment to different APC without explanation
- Pass-through Status of HCPCS code A9583 *Injection, gadofosveset trisodium, 1 mL*
- Hospital Outpatient Quality Reporting Program (Hospital OQR)

Computed Tomography of the Abdomen and Pelvis

The ACR appreciates CMS’ acceptance of our suggestion to create new Ambulatory Payment Classifications (APCs) for the combined Computed Tomography (CT) of the abdomen and pelvis CPT codes (74716, 74177, and 74178) and we ask that this policy be finalized in the 2012 HOPPS Final Rule.

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In the 2011 HOPPS Final Rule, CPT code 74176 was assigned to APC 0332 (Computed Tomography Without Contrast), CPT code 74177 was assigned to APC 0283 (Computed Tomography With Contrast), and CPT code 74178 was assigned to APC 0333 (Computed Tomography Without Contrast Followed by With Contrast). These assignments failed to recognize that each of the new codes reflect the reporting under a single code of two services that were previously reported under two separate CPT codes. The ACR clarified this fact in our comments on the final rule as well as testimony to the APC Advisory Panel and in a meeting with CMS staff. It was suggested that a more accurate payment rate could be established by using claims data that reflect the combined cost of the predecessor codes.

Previously, under the CY 2010 OPSS payment policy, if a patient received abdominal and pelvic CT scans in a single hospital outpatient department encounter, the hospital would bill two separate CPT codes that were paid under composite APCs 8005 (CT and CTA without contrast) or 8006 (CT and CTA with contrast). Under the 2011 interim APC assignments for the new codes, if a patient receives the exact same abdominal and pelvic CT scans in a single hospital outpatient department encounter as was provided in 2010, the payment has been dramatically reduced. Consistent with long-standing CMS payment policy, straightforward coding changes that do not alter the basic description of the service(s) cannot serve as the basis for APC reassignments and result in changes in payment. Therefore, the creation of new APCs 0331 (Combined Abdominal and Pelvis CT Without Contrast) and 0334 (Combined Abdominal and Pelvis CT With Contrast) will result in more appropriate payment rates for these codes.

The ACR would like to continue to have an open dialog with CMS as additional CPT codes are bundled in order to ensure their placement into appropriate APCs.

Endovascular Revascularization of the Lower Extremity

The ACR appreciates CMS' recognition of the two times rule violation and movement of CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s)) from APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) to APC 0229 (Transcatheter Placement of Intravascular Shunt and Stents) and we recommend that this proposed be finalized in the 2012 HOPPS Final Rule.

Reductions that are secondary to new "bundled" CPT codes

APC 0377, Level II Cardiac Imaging, has had a stable payment over the years; however this proposed rule would reduce payment by **11 percent**. This APC now contains four CPT codes that were newly bundled effective 2010. These four codes came out of work by the RAW Committee. The CY 2012 HOPPS Rule is the first year where CMS will have data for these new packaged CPT codes. Hospitals are often slow to update their



charge masters following most coding changes. In reviewing the CMS data for these new codes in the CMS posted cost files, we note that several hospitals did not update their charge masters to reflect an appropriate updated charge reflecting the new bundled and packaged codes.

The ACR believes that CMS can implement dampening policies to assist hospitals from experiencing substantive reductions, while giving the hospitals claims data time to catch up. We believe that the reduction in payment in any one year, following implementation of any new bundled or packaged procedure code, should be limited to 10 percent. We recommend a one to two year “dampening period” beginning with the first year that CMS could utilize claims for rate setting; therefore this would be two years after publication of the new CPT or HCPCS code. This would allow hospitals reasonable time to appropriately update their charge masters to reflect the newly packaged codes. We understand CMS will see more of these packaged codes over time and we believe this policy would assist hospitals by reducing significant fluctuations in rates from year to year.

**Reassignment of procedure to different APC without explanation. CPT 78075
*Adrenal imaging, cortex and/or medulla 29 percent reduction in payment***

The ACR questions the reason for the proposal to reassign the procedure CPT 78075 *Adrenal imaging, cortex and/or medulla* from APC 0408 to APC 0414 Level II Tumor/Infection Imaging. We know of no clinical reason for changing its category. By cost alone, it would appear it should remain in its current APC. The median cost for CPT 78075 (CMS public file) is \$1,269.05; the median cost of a similar procedure, which is in APC 0408, CPT 78804, is \$1,352.17. The ACR requests the CMS to reevaluate the reassignment of CPT code 78075, and consider maintaining its placement in APC 0408. Further, the ACR recommends providing rationale in all proposed rules when any CPT code placement change is proposed.

Pass-through Status of HCPCS code A9583 *Injection, gadofosveset trisodium, 1 mL*

CMS proposes to discontinue pass-through payment for HCPCS code A9583, “Injection, gadofosveset trisodium, 1 mL,” effective for CY 2012. Under the statute, transitional pass-through payments for a drug or biological must be made for at least two years and may be made for a third year after the product’s first payment as a hospital outpatient service. For most pass-through drugs, upon expiration of pass-through status, the drug is paid at the rate established for separately payable drugs and biologicals (proposed as ASP + 4% for CY 2012). For contrast agents, diagnostic radiopharmaceuticals, and implantable biologicals, however, payment for these products is packaged into the payment for the associated procedure, regardless of the per day costs.

We understand that CY 2012 rates for A9583 would be based on CY 2010 utilization and imputed cost data. Also this code has had very low utilization for 2010 because the product was not launched until the first quarter of CY 2010. By limiting pass-through to



two years, CMS will have only one year of hospital claims data to review for purposes of rate setting in CY 2012. Therefore the ACR supports Lantheus Medical Imaging's request for a third year of pass-through payments for gadofosveset (code A9583).

Hospital Outpatient Quality Reporting Program (Hospital OQR)

In this section our comments will address Hospital Outpatient Quality Reporting Program Proposed Expansion of Quality Measures for 2013, 2014, and 2015 Payment Determination, Possible Quality Measures under Consideration, and publication of HOP QDRP data.

Publication of OQR Data

As the ACR has stated previously, until the current and new Outpatient Imaging Efficiency measures have been thoroughly tested and the collection and analyses methodologies validated, CMS should move forward very carefully with public reporting of the data, with particular care in basing statements of "quality" against benchmark rates which may not be substantiated. Keeping the "within range" rates broad during initial implementation is less likely to unfairly represent the performance or quality of facilities and reduce the potential for negatively affecting access to imaging services. *Additionally, the ACR urges CMS to continue using both stakeholder and focus groups for developing and evaluating terminology for presenting measurement data to the public, in order to avoid misleading or alarming patients unnecessarily.* The ACR supports CMS' goal of reducing inappropriate utilization of imaging services, in particular to reduce unnecessary radiation exposure. The imaging measures in the OQR program can complement the ACR's efforts related to appropriate utilization and radiation dose optimization. However, the ACR's approach to educating patients and the public about radiation exposure has focused on a balance between the benefits of imaging as a diagnostic tool with assessing the necessity of the exam. We hope CMS will continue to seek ACR input in the development, implementation and reporting of imaging measures in this program.

Quality Measures for 2012 Payment Determination

CMS proposes to continue with measures previously finalized for the CY 2012 payment determination, and to retain all measures adopted for CY 2011. Imaging measures for CY 2012 payment determination include:

- OP-8 MRI for Lumbar Spine
- OP-9 Mammography Follow up Rates
- OP-10 Abdomen CT Use of Contrast
- OP-11 Thorax CT Use of Contrast
- OP-13 Cardiac imaging for Preoperative Risk Assessment for Non-Cardiac Surgery
- OP-14 Simultaneous use of CT brain and CT sinus



- OP-15 Use of brain CT in ED for atraumatic headache

The ACR recommends that CMS revise measure OP-13 cardiac to add exclusions that would recognize appropriate use of stress imaging in patients with certain clinical events coincidentally around the time of the “non-cardiac” surgery. The American College of Cardiology developed a similar measure (also NQF endorsed) that addresses appropriate cases, although the measure requires chart abstraction or registry data. A current ACC/AHA/ACR/AMA PCPI workgroup is reviewing the ACC measure to potentially specify it for claims.

As stated previously in 2011 rulemaking, the ACR does not support inclusion of the two neurological imaging measures (OP-14 and 15). Our concerns are reiterated below.

First, OP-14, Simultaneous Use of CT Brain and CT Sinus measure has too many similarities with OP-15, Use of Computed Tomography in Emergency Department for Headache measure, increasing burden of analysis for hospitals with little additional information or gain. Also, there may be little yield to this measure; at many facilities the sample size for patients having both scans may be small. Furthermore, many facilities have multi-slice scanners that are capable of reconstructing the data to better evaluate the sinuses without requiring rescanning and without additional radiation. This will ultimately become the norm. However if the measure is used, explicit exclusion criteria should be added for patients with signs of serious infection.

The ACR supports the substance of OP-15, Use of CT in the ED, because it targets an area of known overuse, it is concordant with the ACR Appropriateness criteria, it is actionable by the emergency department (ED), and it serves an independent public health need. Headache continues to account for large numbers of ED visits in the U.S. annually – estimated at approximately 3.1 million per year according to the National Center for Health Statistics (see reference below). There is little doubt that headache imaging in the ED on patients with non-focal neurologic exams yields a low percentage of positive studies and cumulative population radiation dose is a valid concern.

(Nawar EW, Niska RW, Xu J. National Hospital Ambulatory Medical Care Survey:2005 Emergency Dept Summary. Advance data from vital and health statistics; no. 386. Hyattsville, MD ; National Center for Health Statistics, 2007.).

The statement of red flags is appropriate and the exclusion criteria are well thought out. Admission and/or transfer and lumbar puncture are operational indicators of pathology or high likelihood thereof, and the clinical findings of dizziness, paresthesia, lack of coordination, subarachnoid hemorrhage, thunderclap headache should be sensitive, though not specific, indicators of pathology. However, historical features that predict structural pathology such as HIV/AIDS, cancer, visual disturbance, protracted nausea and vomiting should be added to the exclusions, as well as all codes for neurological signs of cerebral origin. To restate, the target population is patients with headache absent neurological signs or other symptoms.



Much of the ED role has evolved to triage serious disease. As such, many studies are performed that are negative, e.g. c-spine x-rays as well as CT for neck pain or discomfort. The imaging findings of occult intracranial hemorrhage or tumors are non-specific and may present as headache. The issue is that imaging is often performed to exclude these unusual but potentially treatable causes. This is further exacerbated by tort systems that seem systematically structured to reach irrational conclusions in individual cases causing ED physicians' fear of missing 'high stakes' abnormalities. The same applies to headache imaging and the fear of missing the brain tumor in the 8 year old, for example.

Serious pathology can present with isolated headache and no focal findings. ED physicians are often overwhelmed by the number of patients presenting to the ED and may not be in a position to carefully and systematically exclude all causes of headache. Moreover, if a patient is not imaged, many simply return to the ED because of anxiety, perceived disability, loss of productivity, etc. This is especially true for the underserved or uninsured/underinsured. Also, patients who are well insured are probably more likely to use the ED when their symptoms are more severe or atypical. It is often more cost-effective to image and exclude serious disease (once and for all) from a societal point of view.

Moreover, a recent study showed that there can be economic value when patients with headache are imaged even when the study is negative. A symptom of headache is often quite ominous and burdensome to the patient, greatly affecting lifestyle, productivity, and sense of wellbeing. If the value of negative studies does not incorporate the value of improved patient function and productivity (that often follows from knowing that the head CT is negative), from a societal point of view, the true value of the imaging, even when negative, will be understated. (Jordan JE, Ramirez GF, Bradley WG, et al. Economic and Outcomes Assessment of MR Imaging in the Evaluation of Headache. JNMA 2000;92:573-578.)

The ACR urges CMS to reconsider the use of OP-15.

Quality Measures for 2013 Payment Determination

CMS proposes to continue with measures previously finalized for the CY 2013 payment determination, and to retain all measures adopted for CY 2012, including a chart-abstracted measure: Emergency Department- Head CT scan results within 45 minutes of arrival for acute ischemic stroke or hemorrhagic stroke patients. The ACR supports this measure.

Possible Quality Measures under Consideration for Future Inclusion in HOQR

CMS provided a list of measures or measure topics under consideration for future years including Breast Cancer Detection Rate. The ACR continues to be concerned that the



Mammography Recall Rate measure that CMS currently includes in HOP QDRP is the sole metric used for assessing mammography performance, and for this reason is encouraged that CMS is considering development and inclusion of a Breast Cancer Detection Rate measure in the HOP QDRP program. We look forward to continued collaboration on this topic with CMS-contracted measure developers.

Conclusion

Thank you for the opportunity to comment on the important issues discussed in this proposed rule. We appreciate CMS' acceptance of our comments on the 2011 final rule and look forward to continuing to work with you on these important payment policies in the future. If you have any questions about our comments, please feel free to contact Kathryn Keysor at 800-227-5463 extension 4950 or via e-mail at kkeysor@acr.org.

Respectfully Submitted,

A handwritten signature in black ink that reads "Harvey L. Neiman, MD". The signature is written in a cursive style.

Harvey L. Neiman, MD, FACR
Chief Executive Officer

cc: Edith Hambrick, MD, CMS
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