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September 14, 2007

Via Electronic Submission to: <http://www.cms.hhs.gov/eRulemaking>

Kerry Weems

Acting Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule CMS-1392-P

Dear Administrator Weems:

The American College of Cardiology (ACC) wishes to express our appreciation for the opportunity to comment on the proposed rule on Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2008 Payment Rates. (72, Federal Register, 42627–43130; No. 148, August 12, 2007).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose purpose is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

CMS has outlined a number of complex and far reaching proposals in the 2008 HOPPS proposed rule. While CMS may have intended to set up a system that encouraged efficiencies in hospital services, ACC believe that the agency may inadvertently create financial incentives for hospitals to utilize the least costly procedure rather than the most appropriate procedure, disregarding patient clinical needs and creating opportunities for decreased quality of care. We request that any new policies proposed by CMS be transparent and provide the clear crosswalks of codes with the data to evaluate the resultant payment.

Data used to determine APC Rates

ACC commends CMS for the significant effort to stabilize the variation in APC payment rates for CY 2008. We continue to advocate for the use of external data to validate rates where existing claims data is inadequate in determining median costs. This is particularly an issue for new procedures, new APC placement of codes and high-cost device-dependent procedures. With claims data that lag up to two years behind the applicable payment period, and even older hospital cost reports, the use of external data could improve the accuracy of payments.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

OPPS Packaged Services

CMS proposes seven new categories and two “composite” categories with wide sweeping bundling changes that warrant a comprehensive and transparent review prior to any proposed implementation. **ACC would encourage CMS not to implement this proposal in 2008 and work with stakeholders for further input.**

The 60-day comment period does not allow sufficient time for us to determine the impact of such wide-sweeping changes on hospitals and patients. In addition, the agency has failed to provide information identifying the APCs in which these costs will be packaged. For instance, CMS has not identified the APC to which several imaging procedures, which are proposed for packaging in 2008, will be assigned. This lack of information makes it difficult to assess and comment on whether the APCs to which these services will be assigned adequately cover their costs. **ACC recommends that CMS be more transparent in identifying and defining the process/policy for defining which APC services are proposed for packaging in 2008.**

Bundling Seven Categories

Image Post Processing Services

CMS is proposing to package payment for "image processing" HCPCS codes for CY 2008, specifically those codes that are reported as supportive dependent services to process and integrate diagnostic test data in the development of images, performed concurrently or after the independent service is complete. Three-D post processing (CPT codes 76376 and 76377) and Doppler color flow add-on (CPT code 93325) will not be paid separately, but will be considered packaged into the services affiliated with their use. **The ACC has multiple concerns with this proposal. First, these services could be reported on the same claim as more than one “base” service. The lack of information of which code has been bundled to makes it difficult to assess and comment on whether the APCs to which these services will be assigned are appropriate. Further, ACC is concerned that hospitals will not place importance on the value of these services and may not continue to support their availability to patients in the hospital.**

Intraoperative Services

CMS is proposing to package payment for "intraoperative" HCPCS codes for CY 2008, specifically those codes that are reported for supportive dependent diagnostic testing or other minor procedures performed during independent procedures. ACC is concerned with a number of issues with this proposal. With respect to echocardiography services, we note that the AMA CPT Editorial Panel has recently approved a new code (which was submitted by the ACC at the urging of the RUC, including the CMS RUC representative), which includes adult TTE

(CPT 93307), spectral Doppler (93320) and color Doppler (93325). The new code is scheduled to become effective in CY 2009. If the Doppler services are bundled into all echocardiography base codes in 2008, the introduction of this new code in CY 2009 is likely to result in substantial confusion among hospitals.

CMS has also proposed to bundle into diagnostic cardiac catheterization codes several rarely used add-on procedures – these include:

- intravascular ultrasound (IVUS - CPT 92978, 92979 & 37250, 37251)
- fractional flow reserve (FFR – CPT 93571 & 93572), and
- intracardiac echocardiography (ICE - CPT 93662)

The procedures included in this section have significant clinical benefits for patients and can even reduce net Medicare expenditures. By providing additional clinical information to cardiologists, these procedures frequently allow physicians to decide against performing an intervention on a patient. Additionally, when an intervention is performed the additional clinical information obtained from the add on procedures listed above is used to assure the most appropriate size and placement of a stent. Optimal sizing and placement of stents is clearly linked to improved patient outcomes and a reduced need for subsequent procedures.

Additionally, we note that hospitals incur significant capital and operational costs to provide these options to patients undergoing cardiovascular interventions and that even with current reimbursement for these procedures, many hospitals do not provide options. **By eliminating separate facility reimbursement for these clinical options, we are concerned that CMS could be limiting treatment options for Medicare beneficiaries.**

ACC reiterates our request that any new system proposed by CMS should be transparent and provide the crosswalks of codes with the data to evaluate the resultant payment.

Imaging supervision and interpretation (S&I) services

Under this 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 OPDS, most commonly injection procedures. **ACC is concerned that if a procedure with status “S”, “T”, “V” or “X” is included in the same claim there would be no payment for the S&I codes. Since patients commonly receive multiple services in hospital OPDs, it appears that CMS would essentially be eliminating payment for large segments of service. The ACC supports the APC Advisory Panel’s recent recommendation to delay implementation of packaging of the S&I codes for 2008.**

Diagnostic Radiopharmaceuticals

In the recent August 12, 2007 proposed HOPPS rule CMS again attempts to reclassify radiopharmaceuticals, this time as “supplies”. **We strongly disagree with this CMS reclassification, as there is clear regulatory guidance that radiopharmaceuticals are indeed drugs and should have payment policies reflected of drugs and NOT supplies.**

Radiopharmaceuticals are administered as part of nuclear medicine diagnostic or therapeutic procedures and are integral to the nuclear medicine procedure itself. “Packaging” diagnostic radiopharmaceutical(s) into the procedure APC does not account for the varying costs and clinical effectiveness of the full range of reasonable clinical alternatives that physicians and hospitals consider in determining the most appropriate drug for each Medicare patient. Bundling may encourage hospitals to use less clinically effective radiopharmaceuticals when there is a choice of radiopharmaceuticals for any one procedure. The published proposal ignores medical indication and focuses solely on cost as the driver. This could result in constraints on medical decision making that may compromise medical care.

Therefore, we urge CMS to continue to treat radiopharmaceuticals as drugs, paying separately and bundling only those under the defined drug cost threshold that both the field and CMS find acceptable. Further, ACC appreciates the APC Panel recommendation to develop separate APCs for radiopharmaceuticals, but are concerned that if pricing ranges are not adequate, then hospitals will put undue pressure on physicians to use a less expensive radiopharmaceutical with nuclear medicine procedures when that drug may not be the most clinically appropriate selection for the patient.

Contrast agents

Under the HOPPS Proposed Rule, hospitals will receive the same payment regardless of whether contrast is used, creating an additional disincentive to use contrast agents. ACC opposes implementation of the policy as proposed. We feel that there are no clear policy guidelines to support treating contrast agents differently than other injectable drugs.

The proposal is particularly problematic for contrast echocardiography. There are no CPT codes that distinguish echo studies performed with contrast from those performed without contrast. The cost of the contrast agent exceeds the \$60 (Q9957)(Inj. perflutren lip micros, ml) threshold proposed to be used by CMS to determine which drugs should be bundled, and also significantly exceeds the cost of most other contrast agents – for example, those generally used with CT and MRI procedures.

The ACC recommends that CMS delay implementation of packaging of contrast media into contrast-enhanced procedures until the agency can provide crosswalks of the APCs into which these drugs are being packaged, an impact analysis of the packaging and a clear explanation of how CMS interprets this to be within its authority under the MMA.

Observation Care

In the proposed rule, CMS proposes to package payment for all observation services reported with HCPCS code G0378 for CY 2008. Payment for observation services would be made as part of the payment for the separately payable independent services with which they are billed. As part of this proposal, CMS would change the status indicator for HCPCS code G0378 from "Q" to "N." **ACC is concerned that the premise to package observation is flawed as observation care is not a dependent service. ACC recommend that the current separate observation payments for congestive heart failure, asthma and chest pain be maintained until CMS conducts further analysis of how packaging observation charges/costs can be packaged into APCs in an appropriate manner.**

Drug and Radiopharmaceutical Handling Cost

The ACC believes that the cost of handling radiopharmaceuticals should be included in the procedure itself. We do not believe nor have we seen any evidence that hospitals have been including handling costs in their reported radiopharmaceutical costs. **Therefore, ACC recommend that the CMS change its instructions for radiopharmaceuticals and inform hospitals to include handling costs in the same manner as they propose to require for drugs in the 2008 final rule.**

Cardiac Rehabilitation Services

The ACC is concerned with the proposed new Medicare policy to change the definition of per-session encounter to a per hour encounter using the new HCPCS G-codes GXXX1 and GXXX2. In well over 95% of clinical situations, those sessions are one hour long, so we believe that very little new data, if any, will be gained by a coding shift that changes a unit from a "session" to an hour. We are also concerned that it will be difficult for hospitals to bill on per session basis for all other payers and on a per-hour basis form CMS as hospitals will not be able to bill all payers the same amount for the exact service. **The ACC supports the APC Advisory Panel's recent recommendation to not implement the GXXX1 and GXXX2 codes and leave services as they are currently in 2007.**

Composite APCs

CMS is also proposing to unconditionally package other CPT codes under the grouping of intra-operative services for the CY 2008 OPSS. These codes (93609, 93613, 93621, 93622, 93623 and 93662) are all CPT add-on codes that are often reported with cardiac electrophysiologic evaluation and ablation services. We are concerned, however, with the packaging of intracardiac echocardiography (CPT 93662) which is reported as an add-on code for cardiac electrophysiology and interventional cardiology procedures that require a transeptal approach. For CPT 93621, 93622, 93651 or 93652, ICE is used to identify the area of the atrial septum where needle puncture can be safely performed. Intracardiac echocardiography is currently paid separately under APC 0670 with a payment rate of \$1984.52. This is a low volume procedure offered only in a limited number of hospitals; therefore, we believe that packaging this low-volume procedure will contribute inadequately to the medians of the composite APC or to the individual APC medians. Furthermore, the impact of the packaged payment for this supportive procedure will be concentrated in the small subset of hospitals that have invested in this expensive technology. We recommend that this procedure continue to be paid separately under the OPSS for CY 2008.

ACC applauds CMS' efforts to promote efficiency and greater stability of payment for services, but are concerned that these proposals may produce artificial reductions in complexity of services provide, with corresponding reductions in payments that will lead to access issues. We recommend that CMS proceed with caution regarding the application of this methodology. Any further development of composite APCs should be accompanied by a clear, transparent process and data for identifying and calculating future composite APCs. Additionally, it is important that composite APCs are designed in a manner that sufficiently accounts for the resources associated with performing the common combinations of services.

Conclusion

Again, ACC appreciates the opportunity to comment on this HOPSS 2008 Proposed Rule. We also appreciate CMS' willingness to continue the dialog with all stakeholders regarding appropriate payment methodologies and appropriate costs associated with cardiovascular procedures provided to Medicare beneficiaries. We encourage CMS to work with all stakeholders during the coming year to develop a more transparent proposal that reflects the input of all stakeholders for CY 2009.

Mr. Kerry Weems
September 14, 2007
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The ACC is ready to discuss any of its comments on the above issues. If you have any questions or concerns, please feel free to contact Denise Garris, American College of Cardiology at 202-375-4696.

Sincerely,

A handwritten signature in black ink that reads "James T. Dove, MD". The signature is written in a cursive style with a large initial "J" and "D".

James T. Dove, MD, F.A.C.C.
President, American College of Cardiology

cc: Kenneth Simon, MD - CMS
Edith Hambrick, MD - CMS
Pam West - CMS
Rick Ensor - CMS
Ken Marsalek - CMS
Jack Lewin, MD, Chief Executive Officer
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