

July 29, 2008

AAMC Summary and Analysis

CALENDAR YEAR 2009 MEDICARE OUTPATIENT PPS PROPOSED RULE: PROVISIONS OF INTEREST TO AAMC MEMBERS

On July 18, 2008, the Centers for Medicare and Medicaid Services (CMS or the Agency) published in the Federal Register, its calendar year 2009 proposed rule for the Medicare hospital outpatient prospective payment system (outpatient PPS or OPPTS): “*Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates ...*” [73 Fed. Reg. 41416]. The proposed rule can be obtained on the AAMC’s web site at:
<http://www.aamc.org/advocacy/teachhosp/outptpps/start.htm>

The proposed rule contains the level of the payment increase (known as the “update factor”) for OPPTS base payment rates, as well as changes and discussions related to: composite Ambulatory Payment Classification (APC) groups for multiple imaging services, the outpatient quality reporting program, payment for drugs, biologicals and radiopharmaceuticals, the evaluation and management codes that hospitals use to report clinic and emergency department visits and critical care services, APC groups and relative weights, device-dependent APCs, and outlier payment policies. If finalized, these policies will take effect January 1, 2009.

In this rule, CMS is also proposing changes to the Ambulatory Surgical Center (ASC) payment system and CY 2009 payment rates, which take effect January 1, 2009. A brief summary of the key changes to the ASC payment system is included at the end of this document.

Comments on the proposed rule are due **September 2, 2008**.

If you choose to submit comments by email, please use the following link:

<http://www.cms.hhs.gov/eRulemaking>

A number of outpatient data tables are available on the CMS web site at:
<http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1213303&intNumPerPage=10>

GENERAL BACKGROUND

On August 1, 2000, Medicare implemented a prospective payment system for hospital outpatient services. The outpatient PPS does not affect Medicare physician payments.

The major categories of services subject to the OPPTS are:

- clinic visits,
- emergency room visits,

- diagnostic services,
- surgical procedures,
- radiology services, and
- cancer chemotherapy.

In general, the outpatient services excluded from the OPSS are those that already are subject to an existing fee schedule or payment system, for example laboratory services. Payments under the OPSS are for individual services (as identified by Healthcare Common Procedure Coding System (HCPCS) or Physicians' Current Procedural Terminology (CPT)).

APC groups are the foundation of the OPSS. In general, hospital outpatient services (as identified by HCPCS/CPT codes) are grouped together under a specific APC according to their similarity in terms of resource costs and clinical indications. In some cases there may be only a few services under a given APC, while in others there may be 50 or more.

In general, each APC is assigned a relative weight based on the median costs of the services in the APC. The relative weight is multiplied by the OPSS "conversion" factor to arrive at a base APC amount. This amount is then adjusted by the hospital wage index, which reflects differences in labor costs across geographic areas. Currently, there is no teaching-related adjustment under the OPSS.

Certain outpatient services have unique payment methodologies. This is true particularly for new outpatient services and certain drugs and devices.

OPSS CONVERSION FACTOR UPDATE AND PAYMENT RATES (pages 41457 and 41557 – 559)

The proposed rule implements the current law requirement that the OPSS base payment rate under (known as the "conversion factor") be increased to reflect the full increase in the hospital inpatient market basket, as published in the FY 2009 inpatient PPS final rule. This increase is 3.0 percent. For hospitals that do not submit the performance data, their payment update will be reduced by two percentage points. However, services that do not utilize a conversion factor are not subject to this reduction policy (see Reporting Quality Data section).

Some of the factors that would affect the actual increase in the conversion factor under the proposed rule are: the difference between the 0.09 percent pass-through dollars set aside in CY 2008 and the 0.07 percent estimate for CY 2009 pass-through spending (see Pass-Through Pool section), the one percent outlier pool and the wage index. CMS estimates that major teaching hospitals would see an overall average increase in OPSS payments of 3.9 percent in 2009, compared to a 3.5 percent increase for both minor teaching hospitals and non-teaching hospitals (see Impact Table 45 on page 41559).

Analysis

CMS estimates that actual average increase in payments for teaching hospitals is higher than the proposed market basket increase because of other proposed changes. Specifically, according to the impact analysis, the Agency estimates that all hospitals would see an increase of 3.4 percent, attributable to the proposed 3.0 percent market basket increase and the 0.4 percent increase in payment weights created by the reduction in payment for partial hospitalization program services that is then redistributed to other services (page 41557). Furthermore, the Agency notes that major teaching hospitals would see a 0.6 percent increase in payments due to APC recalibration and a 0.1 percent decrease in payments due to proposed changes to the wage indices (page 41557).

COMPOSITE APCs (pages 41443 – 451)

Background

In CY 2008, CMS established a new type of service called a “composite APC” that bundles payment for multiple major procedures performed during a single hospital encounter. This differs from non-composite APCs in that payment for non-composite APCs is primarily based on “packaging” payment for minor, ancillary services associated with a significant procedure with the payment for that procedure. Thus, CMS created four composite APCs in CY 2008: APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), APC 8001 (LDR Prostate Brachytherapy Composite), APC 8002 (Level I Extended Assessment & Management Composite), and APC 8003 (Level II Extended Assessment & Management Composite) (72 FR 66650 through 66659).

Multiple Imaging Composite APCs (pages 41447 – 451)

Background

Currently, hospitals receive a full APC payment for each imaging procedure on a claim, even if they occur during the same operative session. In its March 2005 Report to the Congress, MedPAC noted that multiple imaging procedures using the same imaging modality that are performed in a *physician’s office* in the same session are less resource intensive than if they are performed during separate sessions. However, since physicians receive full payment for imaging services, MedPAC concluded that the payment rate does not account for these savings. In light of these findings, MedPAC recommended that CMS reduce the technical component of the physician payment for multiple imaging services performed on contiguous body areas.

Because CMS believed that the same issue is occurring in the hospital outpatient arena, in the CY 2006 OPPS proposed rule, CMS proposed a payment reduction policy when two or more procedures in the same family are performed in the same session. Specifically, CMS proposed that the first procedure would be paid in full, but any subsequent procedure would be paid at a discount of 50 percent. CMS had identified 11 families of imaging procedures, based on the type of imaging modality used and contiguous body area that qualified for the application of the proposed policy.

In response to comments from the AAMC and others, indicating that the OPPS cost-based methodology already incorporates the efficiencies of performing multiple procedures during the same session, CMS rescinded its CY 2006 proposal. Specifically, commenters noted that this cost

efficiency is already built into each hospital's cost structure and therefore the median estimates for single procedures already reflect these changes.¹ Commenters also urged CMS to conduct further analyses of this issue before proposing a reduction in payments for multiple imaging procedures performed in a single session.

Proposed Rule

For CY 2009, CMS is proposing to create five multiple imaging composite APCs for the following three modalities: ultrasound, CT and CTA, and MRI and MRA.² In order to accommodate the statutory requirement that the OPSS provide payment for imaging services provided with contrast and without contrast through separate payment groups, CMS is proposing to create two separate composite APCs for each of the modalities that involve imaging procedures with or without contrast (CT and CTA and MRI and MRA). The Agency would create a separate composite APC for the ultrasound modality. Thus, the five multiple imaging composite APCs would be: APC 8004 (Ultrasound), APC 8005 (CT and CTA without contrast) and APC 8006 (CT and CTA with contrast), APC 8007 (MRI and MRA without contrast) and APC 8008 (MRI and MRA with contrast).

CMS is proposing to base the composite APC payment amount entirely on median costs derived empirically from OPSS claims for multiple imaging services provided in a single session and Medicare cost report data. The composite APC amount would include payment for packaged services furnished on the same date of service as the imaging services included in the composite APC.

Table 8 (page 41451) lists the HCPCS codes that would be included in the composite APC if the hospital bills more than one of the listed HCPCS codes in one imaging family on a single date of service.

If a hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital would receive payment for the with contrast composite APC.

¹ Outpatient service costs, which are the basis for the APC rate determinations, are calculated by multiplying the charges on the claim by the appropriate hospital department's cost-to-charge ratio (CCR). Most hospitals charge the same for single procedures as they charge for any additional procedure performed during a multiple procedure test. To the extent this is the case, the hospital's departmental CCR is lower than it should be because the denominator is higher than it otherwise would be if the hospitals had charged less for the subsequent services. This results in a cost determination at the individual service level that is likely too low for single scans and possibly too high for subsequent scans. As a result, the APC payment rate also is likely too low for single scans, and too high for multiple scans. However, since most hospitals do both single and multiple scans, the overall payments may be adequate.

If CMS had implemented its CY 2006 proposed rule and discontinued subsequent tests performed during multiple procedures, the amount by which the OPSS is overpaying for subsequent scans would have been eliminated. At the same time, single imaging procedure and procedures that receive the full APC payment when they occur in the same session with other imaging procedures would have been underpaid. Consequently, the CY 2006 proposed rule methodology would have underpaid all procedures, whether single procedures or multiple procedures.

² These three modalities reflect services within the 11 imaging families that were subject to the CY 2006 proposed reduction.

If a hospital performs imaging procedures with HCPCS codes from different imaging families, then the hospital would receive payment based on the “sole service” (when only one imaging service was performed during a single session) imaging APCs to which they are proposed for assignment in CY 2009.

The determination of whether various combinations of imaging procedures qualify for a composite APC or a “sole service” APC would be made by the Integrated Outpatient Code Editor (I/OCE).

Analysis

Although CMS acknowledged in the CY 2006 final rule that commenters’ contention that hospitals’ cost structures already account for efficiencies resulting from performing one or more imaging procedures in the same session may be correct, the Agency also expressed concern that these efficiencies may only minimally impact the CCR used to calculate the weight, especially if hospitals report all diagnostic radiology services in one cost center and do not split the costs and charges for advanced imaging with CT, MRI, or ultrasound into separate cost centers. This along with MedPAC’s CY 2008 OPSS comment letter urging CMS to continue conducting analyses to determine whether a multiple procedure payment reduction is warranted, led the Agency to revisit the issue and propose a composite APC methodology to account for efficiencies resulting from performing multiple imaging procedures in the same session.

CMS states that the per service median cost for each of the multiple imaging procedures performed during a single session, and reflected in the composite APC median costs, was modestly less than the median cost when only one imaging service was performed during a single session. According to the Agency, these results are consistent with their expectations, in that, performing multiple imaging procedures in a single session leads to lower costs for each imaging procedure, thereby confirming CMS’s belief that there are efficiencies resulting from performing multiple imaging procedures in a single session.

Thus, CMS believes this proposal is an improvement over the current system which “neither reflects nor promotes the efficiencies” attained by performing multiple imaging procedures during a single session.

REPORTING QUALITY DATA FOR ANNUAL PAYMENT RATE UPDATES (pages 41539 – 41547)

The Tax Relief and Health Care Act of (TRHCA) required CMS to establish a program for reporting on the quality of hospital outpatient care. Similar to the inpatient program, hospitals must submit data on quality performance measures in the hospital outpatient setting in order to receive their full annual payment update. If a hospital does not submit the performance data their payment update will be reduced by two percentage points.

CMS implemented the reporting program in CY 2008 and required the submission of quality data for seven outpatient measures, including five Emergency room measures and two Perioperative care measures. Data collection on these measures began April 2008. CMS is now looking to expand the program and have proposed four claims-based imaging efficiency measures to be required for CY 2010 payment with data collection beginning in CY 2009.

By way of background, CMS contracted with an outside vendor to develop the imaging efficiency measures. The measures are currently being reviewed at the National Quality Forum (NQF) however, the draft report has not yet been released for public comment. Therefore there are no measure specifications or commentary available to the public at this time.

The proposed measures are as follows:

- MRI Lumbar Spine for Low Back Pain
- Mammography Follow-up Rates
- Abdomen CT – Use of Contrast Material
 - Abdomen CT – use of contrast material excluding calculi of the kidneys, ureter and/or urinary tract
 - Abdomen CT – use of contrast material for diagnosis of calculi in the kidneys, ureter and/or urinary tract
- Thorax CT – Use of Contrast Material

Process for Updating Measures

Similar to the proposed IPPS rule, CMS has proposed the establishment of a sub-regulatory process to update measure specifications to existing measures when necessary. The proposal would have NQF update the measure specifications through the measure maintenance process and CMS would post the updated specifications on the QNet website. While the proposed process would add more flexibility and timeliness into the current process, it would not allow for public comment through rulemaking as is currently the case.

Calculation of Reduced National Unadjusted Payment Rates

CMS has developed an alternative approach for reducing the payment update when a hospital does not submit their quality data. Unlike the inpatient payment system where an across the board reduction in the payment update can be utilized the same is not the case for the outpatient payment system. Therefore, CMS has proposed to apply the payment reduction to only those services that utilize a conversion factor in the payment calculation and exclude those services that do not utilize a conversion factor such as the New Technology APCs, separately payable drugs, biologicals and therapeutic radiopharmaceuticals.

Data Validation Requirements and Appeals for CY 2010

There are no validation requirements for payment determinations for CY 2009 since it is the initial year of the reporting program. CMS has now proposed new validation requirements for cases beginning January 2009 to be implemented for CY 2010 payment determinations. The proposal

moves away from the current validation requirements in the inpatient setting where all hospitals are subject to validation and proposes to randomly select 800 hospitals per year for data validation. All hospitals would be eligible for validation but only those 800 selected would actually submit cases for review. Once a hospital is selected then 50 cases would be identified for re-abstraction and data review. Each selected hospital will need to pass the 80% reliability rate for the overall measure and not at the data element level which is the case for the inpatient measures. CMS is also looking at applying the same validation program to the inpatient program in the future.

CMS is soliciting comments on alternative approaches for data validation for CY 2011. Three approaches were proposed that look at either targeting all hospitals for data validation, only hospitals that raise a red flag based on their data, or some combination of the two.

Currently there is no appeals and reconsideration process in the outpatient reporting program. CMS has proposed to develop a mandatory reconsideration and appeals process that would be in place for the CY 2010 payment decisions.

Public Reporting

CMS has proposed that the data collected for the outpatient program will be publicly reported in CY 2010. As in the inpatient program, hospitals would have the opportunity to review the data before it is posted on the website.

Reporting of ASC Quality Data

The Tax Relief and Healthcare Act also authorized the Secretary to establish a similar program for Ambulatory Surgery Centers (ASC). CMS believes that since ASCs are currently working on implementing a new payment system established in CY 2008, and ASCs lack experience in quality reporting, the implementation of the program should be deferred to a later date. At such time CMS will also have had the opportunity to identify measures most appropriate for the ASC setting.

HEALTHCARE ASSOCIATION CONDITIONS (pages 41547 – 41551)

CMS is looking at the possibility of expanding the current Hospital Acquired Conditions program to other settings and most specifically in this rule to the hospital outpatient setting. They are soliciting comments on options and considerations, including statutory authority, related to extending the IPPS hospital-acquired conditions payment provision to the OPSS.

EVALUATION AND MANAGEMENT CODES (E/M) (pages 41505 – 511)

Background

Since the implementation of the OPSS, hospitals have been reporting five resource-based coding levels for clinic visits and five coding levels for emergency department visits using CPT E/M codes. Prior to CY 2007, payment was provided at three APC payment levels such that the two

lowest levels of CPT codes (1 and 2) were assigned to the low-level visit APC, the middle CPT code (3) was assigned to the mid-level visit APC and the two highest levels of CPT codes (4 and 5) were assigned to the high-level visit APC.

The CPT codes that hospitals use for outpatient E/M services were originally designed to reflect the activities of physicians and therefore do not adequately describe the range and mix of services provided by hospitals during these encounters. Consequently, CMS has instructed hospitals to use their own internal guidelines – based on hospital resource use – to determine which CPT level code to report. As a result, there currently is no consistent coding methodology that is used by all hospitals.

Over the years, CMS has been working with various stakeholders, such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA), to develop national coding guidelines. CMS notes however, that this effort has proven to be more challenging than expected. For example, CMS states that based on both public comments and the Agency’s own knowledge of how clinics operate, it seems unlikely that one set of straightforward national guidelines could apply to the reporting of visits in all hospitals and specialty clinics. Furthermore, input from the public and CMS’s own analyses seem to suggest that hospital reporting practices lead to appropriate payment for the hospital resources associated with clinic and emergency department visits. Consequently, to date, CMS has not developed national coding guidelines. Instead CMS has been encouraging hospitals to continue to use their own internal guidelines until national coding guidelines are established. The Agency states that it will continue to study this issue and may propose national coding guidelines in the future.

The CPT definition manual defines “emergency departments” as hospital-based facilities that are open 24 hours a day, 7 days a week, and provide unscheduled episodic services to patients who present for immediate medical attention. According to CMS, an emergency department that satisfies the CPT definition, as well as other requirements, is referred to as a Type A emergency department. An emergency department that does not satisfy the CPT definition (that is, it is not open 24 hours, 7 days a week), but meets other emergency department requirements, is referred to as a Type B emergency department (see page 41505).

Under the OPPS system, CMS has not been able to distinguish, for payment purposes, between hospital resource costs associated with services provided at Type B emergency department visits and the costs of clinic visits. This is because, prior to CY 2007, CMS had been instructing hospitals to report services furnished at Type B emergency departments using CPT clinic visit E/M codes rather than the Type A emergency department visit codes used by emergency departments that are open 24 hours. However, CMS recognized that Type B emergency department visit costs may be greater than the costs hospitals incur for clinic visits, since they are more likely to treat patients that are similar clinically and in terms of resource use to those treated in Type A emergency departments. Still, because they are not open 24 hours, CMS was unsure whether their costs would rise to the level of the costs incurred by Type A emergency departments.

Thus, in CY 2007, in order to collect and analyze the hospital resource costs of visits to Type B emergency departments, CMS implemented a set of five new G-codes for use by Type B

emergency facilities for CY 2007. Cost data for these new Type B emergency department codes are now available for determining payment rates for Type B facilities.

Also, starting in CY 2007, CMS began paying for clinic visits and emergency department visits using five rather than three levels of payment, based on the assignment of the codes to five clinic visit APCs and five emergency department visit APCs. In other words, for each CPT E/M visit clinic code there is a corresponding clinic visit APC payment level and for each Type A CPT E/M emergency department code there is a corresponding emergency department visits APC payment level. For each of the five newly created G-codes representing a Type B emergency department visit there is corresponding newly created clinic visit APC payment level.

Proposed Rule

Visit Reporting Guidelines

The Agency is not proposing national guidelines for CY 2009. In the absence of national guidelines, CMS is proposing to allow hospitals to continue to use their own guidelines.

Payment for clinic and emergency department visits

Clinic visits are paid under the OPSS based on HCPCS codes that distinguish between new and established patients. Based on the April 7, 2000 final rule, CMS considers that an “established” patient from the point of view of a hospital is “one who has a hospital medical record that was created within the past three years.” Currently, CMS pays for clinic visits based on CPT codes that distinguish between new and established patient visits.

CMS is proposing to modify the definitions of “new” and “established” patients for the OPSS. Specifically, an “established” patient would be one who was registered as an inpatient or outpatient within the past three years. CMS is indicating that this definition would make it easier for hospitals to distinguish between “new” and “established” patients for purposes of correctly reporting clinic visits. That is because, under the proposed definition, hospitals only need to determine whether a patient had been registered as a patient within the previous three years. In contrast, under the current definition, a hospital needs to determine the specific clinic where the patient was previously treated in order to find out when the medical record was initially created.

Under the proposed rule, Type A emergency department visits would continue to be paid based on the five emergency department visit APC.

For Type B emergency department visits, CMS is proposing to create four new APCs, which will correspond to the first four levels of G-codes representing the first four levels of Type B visits. Payment for each new Type B emergency room visit APC is higher than payment for the corresponding clinic visit APC level and lower than payment for the corresponding Type A emergency room visit APC level. Payment for level 5 Type B emergency room visits APC would be at the same rate as payment for level 5 Type A emergency department visits APC (see Table 33 on page 41510).

Analysis

Visit Reporting Guidelines

To determine whether the internal guidelines that hospitals currently use to bill clinic and emergency department visits ensure hospitals bill in an appropriate and consistent manner, CMS performed data analyses to study the current distribution of each level of clinic and emergency department visit codes in hospital claims. CMS notes that the distributions are normal and stable over time. According to CMS these data indicate that hospitals, both nationally in the aggregate and grouped by specific hospital classes, were generally billing in an appropriate and consistent manner. Moreover, this indicates that hospitals' own internal guidelines appear to aid them in billing for services in a manner that accurately distinguishes among different levels of services based on associated hospital resources. In light of these results, CMS proposes that hospitals should continue to report visits during CY 2009 according to their own internal guidelines.

Payment for clinic visits

Over the years, CMS has received comments requesting that the Agency eliminate the “new” and “established” patient distinctions in the reporting of hospital clinic visits, due to the difficulty in reporting such visits based on the current definitions. However, CMS has continued to reject this recommendation. The Agency based its decision on the fact that, according to its analyses, hospital claims data consistently indicate that new patients are more resource-intensive than established patients across all visit levels. Consequently, the Agency has continued to study this issue and for CY 2009 proposed a modified definition of what an “established” patient is. According to CMS this definition would reduce hospitals' administrative burden associated with reporting appropriate clinic CPT codes for these patients.

Payment for emergency department visits

According to CMS's analyses, new CY 2007 claims data, which reflect Type B emergency department visits, show that the first four levels of Type B visits are less costly than the first four levels of Type A emergency department visits but more expensive than clinic visits. However, because level 5 Type B emergency visits have similar median costs with level 5 Type A emergency department visits (indicating that they are associated with higher patient severity of illness), CMS is proposing that they receive the same payment rate as the level 5 Type A emergency department visits (Table 32 on page 41509).

CHANGES TO OPPTS OUTLIER POLICIES (pages 41461 – 465)

Background

As with the inpatient PPS, the OPPTS makes additional payments for outpatient services that are extremely costly (“outliers”). In CY 2005, CMS targeted these payments to be two percent of total outpatient payments, financed by a corresponding reduction in the APC conversion factor.

In its March 2004 Report, MedPAC recommended that Congress eliminate the outlier policy under the OPSS. Since this would require a statutory change, CMS instead reduced the outlier payment for CY 2006 and subsequent years by reducing the size of the percentage of total outlier payments from two percent of the aggregate total payments to one percent. For CY 2008, CMS maintained the total outlier payments at one percent of the aggregate total payments.

Outlier eligibility is determined at the individual OPSS service level. In CY 2005, CMS introduced a fixed-dollar threshold in addition to the traditional multiplier threshold to better target outliers to those high cost and complex procedures where a very costly case could present a hospital with significant financial loss. Thus, for CY 2008, the outlier threshold is met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment rate and exceeds the APC payment rate plus a \$1,575 fixed-dollar threshold. The outlier payment is equal to 50 percent of the difference between the cost of the service and 1.75 times the APC payment for the service.

In CY 2008, CMS made some changes to the calculation of the fixed-dollar outlier threshold. Specifically, the Agency began to adjust the overall CCR to reflect anticipated annual decline in overall CCRs and to use CCRs from the most recent update to the Outpatient Provider-Specific File (OPSF) rather than CCRs that CMS calculates internally for rate setting. Thus, under the current methodology, CMS is inflating charges on the CY 2006 claims – the data used to set payment rates for CY 2008 – by the same inflation factor used to estimate the IPSS fixed-dollar threshold as estimated in the FY 2008 IPSS final rule (72 Fed. Reg. at 47418).

Proposed Rule

For CY 2009, CMS is again proposing to allocate only one percent of aggregate total payments for outlier payments. CMS would also set aside 0.07 percent of total outlier payments to Community Mental Health Centers (CMHCs) for partial hospitalization outliers.

CMS proposes to increase the fixed-dollar threshold by \$225 (from \$1,575 to \$1,800), while keeping the multiplier threshold at its current level of 1.75, to meet the one percent threshold. Thus, for CY 2009, payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$1,800 fixed-dollar threshold. The payment percentage would remain the same – 50 percent.

To address some of what CMS calls “vulnerabilities” of the OPSS outlier payment system, the Agency proposes to update regulations to codify two existing longstanding OPSS policies. Specifically, the Agency would revise 42 CFR 419.43 by adding two new paragraphs. Paragraph §419.43(d)(5)(ii) would specify that the overall CCR applied at the time a claim is processed is based on either the most recently settled or tentatively settled cost report, whichever is from the latest cost reporting period. Paragraph §419.43(d)(5)(iii) would describe circumstances in which a Medicare contractor may substitute a statewide average CCR for a hospital’s CCR. This policy is intended to minimize the use of CCRs that are above the mean and was finalized in the CY 2007 final rule, but was not yet codified in the regulations.

The Agency is also proposing two new regulations that would “more fully address vulnerabilities” in the outlier payment system. Thus, the proposed rule would add §419.43(d)(5)(i), which would specify that for services performed starting January 1, 2009, CMS may specify an alternative CCR or the facility may request an alternative CCR under certain circumstances, such as if a facility’s charges have increased at an excessive rate relative to the increase among other hospitals. CMS would allow such a facility to request that its CCR be prospectively adjusted if the facility presents evidence that the overall CCR that is currently used to calculate outlier payments is inaccurate.

CMS would also add §419.43(d)(5)(iv), which would allow Medicare contractors the discretion to reconcile the CCRs in the hospital cost reports under certain circumstances.

The proposed rule would also implement a reconciliation process similar to that implemented by the IPSS in FY 2003 (63 Fed. Reg. at 34494). Specifically, CMS would set reconciliation thresholds which would include a measure of an acceptable percent change in a hospital’s CCR and an amount of outlier payment involved. Furthermore, when the cost report is settled, the overall CCR would be calculated based on the cost report at the time that the cost report coinciding with the service dates is settled.

In order to address a second vulnerability, CMS proposes to adjust the amount of the final outlier payment to reflect what the Agency calls “the time value of the funds for that time period.” Specifically, CMS would add section §419.43(d)(6), which would apply an adjustment to account for the value of the money for the time period in which the money was inappropriately held by the hospital. Under the proposed rule, a similar adjustment would apply to hospitals that received less in outlier payments (before the reconciliation) than they were supposed to.

CMS does not propose a method to determine how the adjustment would be calculated, but it notes that it would be based on a widely available index that would be established in advance by the Secretary and would be applied from the midpoint of the cost reporting period to the date of reconciliation.

CMS is proposing to apply the reconciliation process to services provided starting on January 1, 2009. The Agency is specifically asking for public comments related to the effective date for the reconciliation that would be least administratively burdensome to hospitals.

Analysis

CMS, cites reports published by the HHS Office of the Inspector General (OIG) that found that community mental health centers (CMHCs) took advantage of vulnerabilities of the current system and manipulated their charges in order to inappropriately receive outlier payments. According to the reports, CMHCs increased their billed charges after their CCRs were established to obtain greater outlier payments (DHHS OIG June 2007, A-07-06-0459, page 2).

According to the Agency, one of the greatest vulnerabilities of the current system, lie in the time lag between the CCRs from the latest settled cost report and current charges, which create the potential for hospitals and CMHCs to set their own charges to exploit the delay in calculating new CCRs. CMS states that facilities can increase outlier payments during this time lag by increasing charges significantly in relation to cost increases. This can lead to inappropriately high CCRs

relative to billed charges. Thus, costs are overestimated and the facility receives greater outlier payments.

In response to comments made by the AAMC and others, CMS began publishing total outlier payments as a percent of total expenditures. Thus, for CY 2006, aggregated outlier payments were 1.3 percent of aggregated total OPPS. The Agency's estimate of current total outlier payments as a percent of total CY 2007 payments is approximately 0.9 percent. For CY 2008, CMS estimates that outlier payments would be approximately 0.8 percent of total CY 2008 OPPS payments. CMS states that retroactive adjustments would "undermine the critical predictability aspect of the prospective nature of the OPPS," because hospitals would not be able to approximate the payment they would receive for outlier cases at the time the services are provided.

TRANSITIONAL PASS-THROUGH PAYMENTS (pages 41477 – 478), (pages 41480 – 484) and (41499 – 500)

Background

The OPPS provides that hospitals may receive "pass-through" payments for a limited period of time, from two to three years, for specific items, including new drugs and devices that meet specified criteria.

After the two to three-year period, the device/drug/biological and its associated costs are "packaged into" a current APC or a new APC is created. The two to three-year time frame was established because it generally takes CMS this amount of time to collect the claims data and allow Agency staff to analyze the device/drug/biological costs and incorporate those costs into the APC rate calculations.

A. Pass-through Payments for New Devices (pages a 41477 – 478)

Background

As mandated by law, in April 2001, CMS established "categories" to determine whether a specific device qualifies for transitional payments (this category designation does not apply to drugs and biologicals). If a category qualifies for pass-through status, then all devices that fall within that category receive transitional payments; individual devices cannot independently qualify for these payments.

The criteria for determining whether a device category is eligible for pass-through payments are set forth at 42 CFR §419.66. One of the criteria used to establish a new category of devices for pass-through payment is that the item be surgically inserted or implanted through a surgically created incision.

Starting in CY 2002, CMS has been deducting from the pass-through payments for the device an amount (called the offset amount) equal to the portion of the APC payment amount associated with the device that the new device is replacing.

Proposed rule

CMS would implement its final decision published in the CY 2008 OPPS final rule with comment period and end pass-through status for device category C1821 (Interspinous process distraction device (implantable)) and L8690 (Auditory osseointegrated device, includes all internal and external components), starting in CY 2009.

For CY 2009, there are no new device categories proposed for pass-through payment. However, should a new device category become eligible for pass-through status after the proposed rule was published and before the beginning of CY 2009, CMS would announce the decision to establish a new device category through a transmittal that implements the OPPS update for the applicable quarter.

B. Pass-through Payments for New Drugs, Biologicals and Radiopharmaceutical Agents (pages 41480– 484)

Proposed rule

Under the proposed rule, pass-through status for 15 drugs and biologicals would expire starting in CY 2009 (Table 20 at page 41482). Pass-through status for 16 drugs and biologicals (Table 21 at page 41483) would continue in CY 2009.

The Medicare Modernization Act (MMA) mandated that payment for drugs and biologicals be based on the competitive acquisition program (CAP) methodology. This is an alternative payment methodology that CMS implemented on July 1, 2006, to enable physicians who cannot purchase drugs and biologicals at ASP plus six (the current reimbursement rate for drugs and biologicals in the physician's office setting) to obtain these drugs and biologicals. Currently approximately 190 of the most commonly provided drugs in the physicians' office setting, are covered under the Part B drug CAP³. Only two – HCPCS codes C9240 and J3488 – of the 16 drugs with pass-through status will be covered under the competitive acquisition program in CY 2009 (Table 21 on page 41483).

For the other drugs and biologicals with pass-through status – that are not part of the Part B drug CAP – CMS is proposing to base their payment rates at a rate that is equivalent to the payment that is being made in the physician office setting, currently set at average sales price (ASP) plus six percent.

There are no radiopharmaceuticals that are eligible for pass-through payment at this time.

C. Pass-Through Payment Pool (pages 41482 and 41499 – 500)

³ The Part B drug CAP rate is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and year established under such sections as calculated and adjusted by the Secretary.

Pursuant to current law, CMS is authorized to spend up to two percent of total OPPS payments for pass-through payments.⁴ CMS estimates however, that in CY 2009, only 0.07 percent of total OPPS payments will be needed for pass-through payments. This figure includes CMS's estimates for the device categories that may become eligible for pass-through status after the proposed rule was published and before the beginning of CY 2009 (estimated at \$10.0 million); projections for the 16 drugs and biologicals eligible for pass-through payments in CY 2009 (estimated at \$3.4 million) as well as estimates for any drugs and biologicals that may become eligible for pass-through payments after the proposed rule was published and before the beginning of CY 2009 (estimated at \$5.5 million in CY 2009). Accordingly, the OPPS conversion factor will be reduced by only 0.07 percent.

OPPS PAYMENTS FOR CURRENT DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS (pages 41484 – 41499)

Background

Items that do not have pass-through status are paid in one of two ways: packaged payment and separate payment. While CMS believes that packaging the costs of items into the payment for the procedure with which they are associated encourages hospital efficiencies, the Agency recognizes that expensive and rarely used drugs, biologicals and radiopharmaceuticals need to be paid separately in order to prevent insufficient payment to hospitals. The MMA provided that a threshold of \$50 be applied, so that items whose cost per day is less than \$50 are packaged with the procedures with which they are billed and those whose cost exceeds \$50 per day are paid separately. However, the \$50 threshold requirement expired at the end of CY 2006.

Thus, for CY 2007 and subsequent years, CMS is updating the threshold for inflation using an inflation adjustment factor based on the Producer Price Index (PPI) for prescription preparations. The adjusted dollar amount is rounded to the nearest \$5 increment. Thus, in CY 2008, the packaging threshold is \$60.

CMS has also created APCs for certain products, rather than packaging them with their associated outpatient procedure. These items include: orphan drugs, blood and blood products, certain vaccines and devices of brachytherapy consisting of a seed or seeds.

The MMA provided that for CY 2006 and subsequent years, payment for separately payable drugs, biologicals and radiopharmaceuticals be equal to the average acquisition cost for the drug for that year, subject to any adjustment for overhead costs.

⁴ Under the payment methodology for pass-through drugs and biologicals, the payment pool for new drugs and biologicals is determined by the difference between the amount authorized under section 1842 (o) of the Act (or, if applicable, the Part B drug CAP rate) and the otherwise applicable fee schedule amount associated with the drug or biological.

For CY 2009, CMS will set the payment rate for pass-through drugs and biologicals at ASP plus six percent which represents the amount authorized under section 1842 (o) of the Act. The Agency, also proposes to pay for separately payable drugs and biologicals without pass-through status at ASP plus four percent, which represents the otherwise applicable fee schedule amount associated with the drug or biological. Thus the difference is not zero and represents the pass-through payment pool for CY 2009 (page 41482 and 41499).

Separately Payable Drugs and Biologicals

Based on its analyses, CMS determined that the average acquisition costs for separately payable drugs and biologicals and their associated overhead costs would best be represented by the average sales price (ASP). Thus, since CY 2006, CMS has been reimbursing separately payable drugs and biologicals based on the ASP methodology. For CY 2008, separately payable drugs and biologicals are reimbursed at ASP plus five percent, a one percent lower payment rate than the payment rate hospitals received in CY 2007. It also is one percent lower than the physician office setting payment rate of ASP plus six percent.

For drugs and biologicals for which CMS does not have ASP data, the Agency uses the mean costs from the CY 2006 hospital claims data as their payment rates for CY 2008.

Radiopharmaceuticals

Beginning in the CY 2005 final rule, CMS exempted radiopharmaceutical manufacturers from reporting ASP data under OPSS. Since the Agency did not have ASP data to set payment rates for radiopharmaceuticals based on the ASP methodology, for CY 2006 and CY 2007 CMS instituted a temporary policy whereby separately payable radiopharmaceuticals were paid on a cost basis; that is, each hospital received a different payment rate based on the claim's charges and the hospital's overall CCR.

CMS learned from the CY 2006 proposed rule comments that not all radiopharmaceuticals' handling costs were included in hospital charges. In order for CMS to provide payment for radiopharmaceuticals that would best reflect hospital acquisition cost and pharmacy overhead costs for each radiopharmaceutical, beginning in CY 2006, CMS instructed hospitals to include charges for radiopharmaceutical handling in their charges for the radiopharmaceutical.

In CY 2008, the Agency began to apply different payment policies to diagnostic radiopharmaceuticals and contrast agents compared to therapeutic radiopharmaceuticals. As part of CMS's increased effort to increase the number of services included under a single APC payment group, the Agency began packaging payment for what CMS deemed "ancillary and supportive" services into the APC payment group for the primary procedure with which they are performed. According to CMS, all diagnostic radiopharmaceuticals are intended to be used with a diagnostic nuclear medicine procedure and therefore considered supportive and ancillary to the primary procedure. Thus, in CY 2008, the Agency packaged all diagnostic radiopharmaceuticals and contrast agents, that were previously paid separately, including those with per day costs over \$60, into the diagnostic nuclear medicine procedure that they are associated with.

Since therapeutic radiopharmaceuticals are considered primary procedures, CMS continues to reimburse them on a separate basis. Thus, in CY 2008, CMS based payment rates for therapeutic radiopharmaceuticals on hospital claims data from CY 2006. Due to the

improvement in reporting charges for radiopharmaceuticals and their associated costs as a result of the CY 2006 instructions, the Agency believes that the CY 2006 claims data reflect both the radiopharmaceutical charge and the associated overhead charges.

In the CY 2008 final rule, CMS established a prospective payment for therapeutic radiopharmaceuticals whereby hospitals would receive an average payment for radiopharmaceuticals and their associated handling costs. Because CMS still does not have ASP data for radiopharmaceuticals, payment would be based on aggregated hospital mean costs as derived from the CY 2006 claims data. The costs in the claims data would be determined by applying hospital-specific departmental CCRs to radiopharmaceutical charges. If departmental CCRs are not available, CMS would use hospital-specific overall CCRs.

However, the Medicare, Medicaid, and SCHIP Extension Act of 2007, requires CMS to pay for therapeutic radiopharmaceuticals for the period of January 1, 2008 through June 30, 2008 at hospitals' charges adjusted to costs. Therefore, for the first six months of CY 2008, hospitals have been reimbursed for therapeutic radiopharmaceuticals on a cost basis. The prospective payment rates were supposed to take effect July 1, 2008 (see Change Request (CR) 5912). However, the Medicare Improvements for Patients and Providers Act of 2008, which became law on July 15, 2008, extends the cost-based methodology for determining payment for therapeutic radiopharmaceuticals until January 1, 2010.

Proposed Rule

The proposed packaging threshold for CY 2009 would again equal \$60.⁵ Drugs, biologicals and therapeutic radiopharmaceuticals whose cost per day is less than \$60 would be packaged with the procedures with which they are billed and those whose cost exceeds \$60 would be paid separately.

Diagnostic radiopharmaceuticals would continue to be packaged into the diagnostic nuclear medicine procedure that they are associated with, regardless of their costs.

For CY 2009, CMS is proposing to package payment for any biological without pass-through status that is surgically inserted or implanted (through a surgical incision or a natural orifice) into the payment for the associated surgical procedure. According to CMS, this policy is consistent with the payment policy for implantable devices. Specifically, the Agency packages payment for implantable devices without pass-through status into the costs of the procedures with which the devices was reported in the claims data.

Because in some cases, implantable biologicals may be used as implantable devices, CMS would instruct hospitals to bill separately for the HCPCS codes for the products when used as implantable

⁵ CMS based its proposed threshold on the most up-to-date forecasted, quarterly PPI estimates from CMS's Office of the Actuary (page 41485). The packaging threshold has not changed since CY 2008 due to rounding. For CY 2008, the threshold was rounded up (from \$57.78 to \$60, which is the nearest \$5 increment), while for CY 2009 the threshold is rounded down (from \$61.25 to \$60, again, the nearest \$5 increment).

devices, thereby ensuring that their costs are appropriately packaged into the associated implantation procedures.

Separately Payable Drugs, Biologicals

Proposed Rule

CMS used manufacturer-submitted ASP data from the fourth quarter of CY 2007, the most current ASP data available, as well as mean costs derived from the CY 2007 hospital claims data, to calculate payment rates for drugs and biologicals in the proposed rule. However, since new data will become available by the time the final rule is published, CMS proposes to use ASP data from the first quarter of CY 2008, as well as mean costs derived from the CY 2007 updated hospital claims data, to set the payment rates for drugs and biologicals that will be published in the CY 2009 OPPS final rule.

For CY 2009, CMS proposes to use the same methodology that it used in CY 2008 to set payment rates for separately payable drugs and biologicals for which ASP data are available. According to CMS, CY 2007 claims data indicate that mean costs are equal to ASP plus four percent. Therefore CMS proposes a payment rate of ASP plus four percent to cover the acquisition and handling costs for drugs and biologicals. This constitutes a one percent payment reduction from the payment rate hospitals receive in 2008 for drugs and biologicals. It is also two percent lower than the payment rate received by drugs and biologicals in the physicians' office setting, which is ASP plus six percent for CY 2009.

For drugs and biologicals for which ASP data are not available, CMS is proposing to use their mean costs from the CY 2007 hospital claims data as their payment rate. In order to better account for the pharmacy overhead costs for drugs and biologicals, CMS is proposing to create two new cost centers when the Agency revises the Medicare hospital cost report form. Specifically, CMS would break cost center 5600 (Drugs Charged to Patients) into two cost centers: Drugs with High Overhead Cost Charged to Patients and Drugs with Low Overhead Cost Charged to Patients. Currently revenue codes 025X and 063X⁶ map to cost center 5600. That is, CMS estimates costs for separately payable drugs and biologicals from charges billed with these revenue codes and applying the CCR for cost center 5600.

Under the proposed rule, the Agency would instruct hospitals to report the charges for drugs and biologicals with high overhead costs under revenue code 0636 (Drugs requiring detail coding). Drugs and biologicals with low overhead costs would be reported under revenue codes 025X and 063X (other than 0636). In order to determine the drug acquisition and pharmacy overhead costs, CMS would map the charges under revenue code 0636 to the new cost center Drugs with High Overhead Cost Charged to Patients, while mapping revenue codes 025X and 063X (other than 0636) to the new cost center Drugs with Low Overhead Cost Charged to Patients.

⁶ For simplification purposes, X stands for a series of numbers that indicate subcategories of a particular revenue code category. Specifically, the revenue code category "Pharmacy" has 10 subcategories indicated by revenue codes 0250, 0251, 0252...0259. Similarly, the revenue code category "Drugs Require Specific ID" has 7 subcategories indicated by revenue codes: 0631, 0632...0637.

CMS would also instruct hospitals to report charges for drugs and biologicals meeting the criteria for the proposed Drugs with High Overhead Costs Charged to Patients cost center under revenue code 0636 for both inpatient and outpatient claims. Currently, hospitals bill outpatient drugs and biologicals charges with revenue code 0636, but there is no such requirement for hospitals to bill inpatient drugs and biologicals charges with revenue code 0636.

In order to determine how to assign drugs and biologicals to the most appropriate cost center that would help CMS better account for the pharmacy overhead costs for drugs and biologicals, the proposed rule discusses and seeks comments on the following four approaches:

1. Require hospitals to report the costs and charges associated with revenue code 0636 in the proposed new cost center Drugs with High Overhead Cost Charged to Patients
2. Set a cost threshold for drug acquisition cost and overhead for purposes of determining which cost centers to use (e.g. packaging threshold for \$60). This would require hospitals to identify the pharmacy acquisition costs and overhead associated with each drug.
3. Set a cost threshold for pharmacy overhead to separate drugs with high versus low overhead. This would require hospitals to identify the pharmacy overhead associated with each drug or biological.
4. Use the categories discussed in the CY 2006 final rule (see Table 24 on page 41488). Categories 1 and 2 would be billed under 025X or 063X and be captured on the cost report in the new cost center Drugs with Low Overhead Cost Charged to Patients. Drugs and biologicals falling into category 3 would be billed under revenue code 0636 and reported in the new cost center Drugs with High Overhead Cost Charged to Patients.

The Agency notes that the data from this proposed policy would not be available until 2010.

The Stakeholder's Approach

The proposed rule includes a stakeholders'⁷ proposal presented at the March 2008 APC Panel meeting. CMS is not proposing this methodology, but it is seeking comments on it.

The stakeholders explained that CMS's methodology of packaging payment for drugs and biologicals with an estimated per day cost of \$60 or less and estimating the equivalent average ASP-based amount based only on the costs of separately payable drugs leads to an inaccurate determination of the acquisition and pharmacy overhead cost for separately payable drugs and biologicals. That is because the CCR used by CMS to determine the acquisition and pharmacy overhead costs does not take into account that hospitals allocate a greater relative share of pharmacy overhead cost to the lower-priced packaged drugs and a lower relative share of pharmacy overhead cost to the more expensive, separately payable drugs. When CMS packages drugs and biologicals with high overhead cost, some pharmacy overhead cost that should be associated with separately payable drugs is being

⁷ Their names were not published in the proposed rule

packaged into payment for the procedures that are performed with lower cost packaged drugs. Thus, CMS's methodology of estimating the acquisition and pharmacy overhead cost for separately payable drugs and biologicals based only on the costs for separately payable drugs and biologicals, does not include overhead costs that should be associated with separately payable drugs and biologicals.

The stakeholder proposal suggested that CMS instead, recalculate the equivalent average ASP-based amount based on the costs of packaged and separately payable drugs with HCPCS codes. CMS could then use this equivalent average ASP-based amount (or the physician's office payment rate of ASP+6 percent) to represent the acquisition and pharmacy overhead cost of all packaged drugs. This amount, which would better reflect the acquisition and overhead costs of packaged drugs, would be included into the payment for the procedures associated with packaged drugs.

Since these changes would be budget neutral, the pool of money resulting from this methodology, could then be distributed in a number of ways. For example, CMS could increase the combined acquisition and overhead cost payment for separately payable drugs to a higher average ASP-based amount and/or provide separate payment for pharmacy overhead costs for either all drugs or only separately payable drugs based on a flat add-on rate or on tiers of pharmacy service complexity.

According to the stakeholders' analyses, the APC median cost estimates demonstrate that their recommendation would significantly impact drug payment rates but would only change the majority of APC median costs by less than 2 percent.

Analysis

Because the findings from a MedPAC survey indicated that hospitals set charges for drugs and biologicals high enough to reflect their pharmacy handling costs as well as their acquisition costs, CMS believes that the current policy of setting payment for these items based on the ASP is the best currently available proxy for average hospital acquisition cost and associated pharmacy overhead costs.

However, since the implementation of the ASP-based methodology for calculating the average hospital acquisition cost and associated pharmacy overhead costs, CMS has received numerous comments expressing concern that the ASP-based methodology does not accurately reflect hospital acquisition and pharmacy overhead costs, especially for drugs and biologicals with high overhead costs. According to CMS, that is because hospitals redistribute the cost of pharmacy overhead from expensive to inexpensive drugs when setting charges for drugs and biologicals. This practice of applying higher percentage mark-ups to relatively lower cost items and lower percentage mark-ups to higher cost items is called "charge compression." Because CMS cannot directly determine the cost of services, it instead "estimates" those costs by applying cost-to-charge ratios (CCRs) that are derived from hospitals' Medicare reports. To the extent that the costs and charges of both types of items are reflected in the calculation of a particular CCR (i.e. the CCR is an average of both low and high mark-up items), this methodology can

result in an inaccurate estimation of costs by either artificially understating or overstating cost estimates.

Recognizing the likelihood of this phenomenon on the inpatient side, CMS awarded a study to RTI International to study methods for improving the accuracy of the adjustment of charges to costs for both inpatient and outpatient services. As a result of the recently completed study for the outpatient PPS, the Agency is proposing to break cost center 5600 (Drugs Charge to Patients) into two new cost centers in order to separate costs and charges for drugs and biologicals with high overhead costs from those with low overhead costs.

Previous proposals to report pharmacy overhead costs separately from drugs and biologicals' costs have raised concerns from numerous commenters about the administrative burden that it would impose on providers. One concern is that these proposals require hospitals to modify their billing systems to separate the pharmacy overhead charge from the drug charge for Medicare claims, but bill them as a single line item for other payers.

CMS is asking for comments on its proposal to add the two cost centers to the cost report. Furthermore, the Agency is specifically requesting input from hospitals with regard to the four approaches intended to determine how to assign drugs and biologicals to the most appropriate cost center.

The AAMC is also interested in members' views with regard to the feasibility and/or administrative burden that would be associated with CMS's proposal to split cost center 5600 (Drugs Charged to Patients) into two cost centers and CMS's proposed approaches to determine how to define the cost centers.

It is unclear what CMS considers to be "pharmacy overhead." CMS seems to assume that overhead is allocated in the same manner that markup is determined. For example, CMS states that "hospitals have informed us that they redistribute the cost of pharmacy overhead from expensive to inexpensive drugs when setting charges for drugs" (page 41490). Furthermore, different hospitals may have very different markups for the same drug or biological from other hospitals. Specifically, the type and volume of patients, may determine how a hospital marks up a certain drug or biological, especially one that requires relatively high resources to store and preserve. For example, a hospital that treats few patients who need a drug or biological that it is expensive to store and preserve may use a higher mark up than a hospital that has a higher volume of patients who need the drug or biological. We are interested in your comments or insight with regard to whether and what type of relationship there may be between pharmacy overhead costs and the charges hospitals set in order to cover the cost of drugs and biologicals and their associated overhead costs.

The Stakeholder's Approach

The APC Panel recommended that CMS work with stakeholders to determine the validity of this methodology and conduct an impact analysis for 2009. Although this approach

would be administratively simple for hospitals to implement, and would refine the methodology for estimating pharmacy overhead cost in a budget neutral manner, without redistributing money from the payment for nondrug components of other services to payment for drugs, CMS did not propose this approach. CMS justifies its decision to not propose the stakeholders' approach on the fact that it would represent a departure from CMS's established methodology. That is because CMS currently uses hospital charge data as it is reported on claims to capture the variability in hospitals' unique charges. The stakeholders' approach would change that. The Agency would substitute an average ASP-based amount (or the physician's office payment rate of ASP plus six percent for the charges on claims when packaging drug costs into their associated procedures. CMS believes that this approach would eliminate the expected variability in hospital's costs of drugs that are packaged into their associated procedures.

Therapeutic Radiopharmaceuticals

Pursuant to the newly passed law, the cost-based methodology for determining payment for therapeutic radiopharmaceuticals will continue to be used until January 1, 2010 (please see the Background section for Radiopharmaceuticals). While the proposed rule provisions have been overridden by the July 15, 2008 law, for those of you who may be interested in what CMS is thinking, we are providing a summary and analysis of the proposed rule below.

[Proposed Rule

For CY 2009, CMS would use ASP data for a radiopharmaceutical only if all manufacturers submit ASP information for that radiopharmaceutical. CMS states that the ASP data would need to be provided for a patient-specific dose, or patient-ready form of the radiopharmaceutical in order for CMS to calculate the ASP amount for a HCPCS code. Furthermore, the Agency notes that manufacturers would also need to provide information that would allow CMS to calculate a unit dose cost estimate based on the HCPCS code for the therapeutic radiopharmaceutical.

As with separately payable drugs and biologicals, CMS is proposing to update the payment rates for therapeutic radiopharmaceuticals quarterly, as new ASP data become available. CMS notes that in order for a therapeutic radiopharmaceutical to receive payment based on ASP beginning January 1, 2009, manufacturers would need to submit ASP data in October 2008. The Agency is proposing to "allow" rather than compel manufacturers to submit ASP data.

CMS would provide payment for therapeutic radiopharmaceuticals without ASP data based on a prospective system that uses aggregate hospital mean costs from CY 2007 claims data to set payment rates. Thus, the Agency would estimate costs from the claims data by applying hospital-specific departmental CCRs to radiopharmaceutical charges. If departmental CCRs are not available, CMS would use hospital-specific overall CCRs.

Analysis

Because CMS instructed hospitals to include charges for handling of radiopharmaceuticals in their charges for the radiopharmaceutical products in CY 2006, the Agency believes that those claims data reflect both the radiopharmaceutical charges and associated handling charges, and thus constitute an adequate proxy for the average acquisition cost of radiopharmaceuticals.

Since CY 2006, CMS has been trying to implement a prospective payment policy that would account for both the radiopharmaceutical cost and its associated overhead cost. After considering and rejecting several alternatives over the years, in the CY 2008 final rule, CMS specifically solicited comments regarding the use of current ASP methodology for setting payment rates that would cover the average acquisition cost of radiopharmaceuticals and their associated overhead costs. CMS rejected recommendations from commenters that involved the use of external data and instead stated that the use of ASP data “would provide an opportunity to improve payment accuracy for these products by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals.” Furthermore, CMS notes that its proposed methodologies of reimbursing therapeutic radiopharmaceuticals for which ASP data are available based on the ASP methodology, while providing payment for therapeutic radiopharmaceuticals without ASP data based on aggregate hospital mean costs from CY 2007 claims data, represent “an appropriate and adequate proxy for average hospital acquisition cost and associated handling costs for these products.”]

Drugs, biologicals and radiopharmaceuticals that have HCPCS codes, but no claims data (pages 41496 – 499)

Background

In CY 2008 CMS implemented an APC Panel recommendation to allow hospitals to report all HCPCS codes for drugs, regardless of the unit determination in the HCPCS code descriptor. This proposal is the result of comments received in the past by CMS indicating that this policy change would reduce the administrative burden on hospitals. Prior to CY 2008 hospitals were allowed to report only the lowest unit determination in the code descriptors, even when a higher unit determination was used. Hospitals then billed the appropriate number of units, that is, they billed the lowest unit determination as many times as necessary to add up to the number of units that were used. CMS assigned these codes the same status indicator as that used for the lowest dose, because the Agency does not have claims data to determine their packaging status. CMS is proposing to continue this methodology in CY 2009.

In CY 2008 CMS is paying for new drugs and biologicals that have HCPCS codes, but no hospitals claims data at ASP plus five percent, the same as it pays for separately payable drugs and biologicals for which there is claims data. For drugs and biologicals for which CMS does not have ASP data, payment is provided based on the wholesale acquisition cost

(WAC) for the product. If the WAC is not available, CMS would make payment at 95 percent of the product's most recent average wholesale price (AWP).

Proposed Rule

For CY 2009, CMS is proposing to continue the CY 2008 policy of reimbursing new drugs and biologicals that have HCPCS codes, but no hospitals claims data at the same rate as provided for separately payable drugs and biologicals with claims data (ASP plus four percent). CMS is also proposing to base payment for new therapeutic radiopharmaceuticals that have HCPCS codes, but no hospitals claims data on the same methodology as that used to determine payment for new drugs and biologicals that have HCPCS codes, but no hospital claims data.

NEW TECHNOLOGY APCs (pages 41470 - 471)

Background

CMS makes special temporary additional payments for new technology items and services until it gathers sufficient data to be able to assign the services to a clinically appropriate APC. As an alternative to granting pass-through status, CMS may decide to assign a new technology to a "new technology" APC. The policy allows CMS to move a service from the New Technology APC and place it with a procedure under a clinical APC in less than two years or retain it in a New Technology APC for more than three years depending on whether it has sufficient data to be able to make a decision for reassignment. By contrast, devices with a pass-through status are required to retain that status for at least two years and not more than three.

Unlike other APCs, new technology APCs are defined based on "cost bands" rather than clinical descriptors. Currently, there are technology APCs in \$10, \$50, \$100 and \$500 increments, ranging from: \$0 to \$10 to \$9,500 to \$10,000. The APC payment rate is the median of the cost band (i.e. \$5 for the \$0 to \$10 cost band).

Proposed Rule

CMS is proposing to move three procedures from New Technology APCs to Clinical APCs that contain services exhibiting clinical and resource homogeneity. Thus, HCPCS codes C9725 (Placement of endorectal intracavitary applicator for high intensity brachytherapy), C9726 (Placement and removal (if performed) of applicator into breast for radiation therapy), and C9727 (Insertion of implants into the soft palate; minimum of three implants) CY 2009 (see Table 14 at page 41471). The reason for the reassignment to a clinical APC is that these three procedures have been assigned to New Technology APCs for at least three years, thereby providing CMS with sufficient data from at least two years of hospital claims, which would be used to determine the appropriate reassignments.

The proposed rule would also delete HCPCS code C9723 (Dynamic infrared blood perfusion imaging (diri)).

Analysis

The movement from New Technology APCs to Clinical APCs would result in payment reductions for two of the three procedures currently in New Technology APCs and a payment increase for one procedure. In CY 2008, HCPCS codes C9725 and C9727 receive a \$550 and \$850 payment respectively based on the New Technology APCs 1507 and 1510. In CY 2009, these codes would be assigned to clinical APC 164 and 0252 respectively and would receive a \$144.92 and \$509.08 payment. This represents a 74 percent and a 40 percent respectively decrease in payments for these codes. One code would experience a 117 percent increase in payments (from \$650 in New Technology APC 1508 to \$1,412.23 in clinical APC 0028) as a result of its reassignment to a clinical APC.

ADJUSTMENT TO APC PAYMENT FOR REPLACED DEVICES THAT RECEIVE PARTIAL OR FULL CREDIT (pages 41478 – 480)

Background

Certain APCs are populated by codes that usually, but not always, require that a device be implanted or used to perform the procedure. Over the years, CMS has used both external data and Medicare claims data to establish APC median costs for APCs that contain outpatient services that involve devices, largely because of variation in hospitals' coding of devices. That is, not all hospitals have been including a device code on a claim, even when a device was used. Thus, it was often unclear whether a hospital's cost for an outpatient procedure on a claim included a device or not, making it difficult to determine accurate costs for procedures that include devices, solely from Medicare claims data. This issue became further complicated when CMS made the use of device codes optional prior to CY 2005. CMS reinstated mandatory device coding in CY 2005. This editing however, was phased in during CY 2005, in that, it began in April and ended in October. Therefore, CY 2006 was the first full year of procedure-to-device edits, which ensured that the charges for the devices were reported on the claims for the procedures using those devices.

In recent years, some devices have been recalled and the manufacturers have offered replacement devices at no cost to the hospital or a credit for the device being replaced if the patient received a more expensive device. Thus, as of CY 2007, in order to identify devices for which the hospital incurs no expense for a defective device that has been replaced, and to set payment rates for device-dependent APCs that contain such devices, CMS requires hospitals to use modifier "FB" for procedures that used these devices and authorized hospitals to charge less than \$1.01 for these items. Starting in CY 2008, CMS expanded its policy to reduce the APC payment for selected device-dependent APCs when the hospital receives a partial credit of 50 percent or more of the cost of a defective device. Thus, the Agency requires hospitals to report the FC modifier for those cases in which a hospital receives a partial credit toward the replacement of a defective device.

CMS chose the device-dependent APCs that were subject to the reduction policy based on three criteria:

- a) all procedures assigned to the selected APCs must require implantable devices that would be reported if device insertion procedures were performed;
- b) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedures (at least temporarily);
- c) the device offset amount for the APC must be significant, i.e. it exceeds 40 percent of the cost of the APC.

CMS implements a policy that reduces the payment for selected device-dependent APCs when the hospital receives certain replacement devices without cost or receives a full or partial credit for the device being replaced. Beginning in CY 2007, payment for device-dependent APCs associated with devices for which hospitals receive replacement devices without cost or receive a full credit for the device being replaced is reduced by an amount based on an estimate of the device cost. This amount is calculated in the same manner as the offset amount that would be applied if the implantable device assigned to the APC had pass-through status as defined under §419.66. That is, the offset amount is determined by first calculating an APC median cost that includes the device cost and an APC median cost that excludes the device cost. Then the percent of cost attributable to the device for which the hospital incurs no cost is calculated by subtracting from 100 the percentage obtained by dividing the APC median cost without the device by the APC median cost with the device. To determine the offset amount, CMS applied this percent to the payment rate of the APC.

Since CY 2008, payment for the device-dependent APCs associated with devices for which hospitals have received partial credit for their replacement is reduced by 50 percent of the device offset that applies when the hospital receives a device at no cost or receives full credit.

Proposed Rule

Table 18 (at page 41479) lists the APCs to which the reduction policy for full credit/no cost and partial credit devices would apply in CY 2009 and displays the proposed payment reduction percentages. Table 19 (at page 41480) lists the devices for which the FB modifier or the FC partial credit modifier must be reported with the procedure code. These include two new APCs.

In order to determine whether the APCs that were subject to the reduction policy in CY 2008 continue to meet the criteria for reduction in CY 2009, and to determine whether other APCs that were not subject to the reduction policy in CY 2008 would meet the criteria for reduction in CY 2009, CMS examined the offset amounts calculated from the CY 2007 claims data available for this proposed rule. Thus, the Agency proposes to add two APCs – APC 0425 (Level II Arthroplasty or Implantation with Prosthesis) and APC 0648 (Level IV Breast Surgery) – and their associated devices. These APCs meet the criteria for inclusion in the list of APCs that are subject to the reduction policy, because the device offset percentages for these APCs are above the 40 percent threshold.

CMS also proposes to remove APC 0106 (Insertion/Replacement of Pacemaker Leads and/or Electrodes) and device HCPCS codes associated only with procedures assigned to this APC because the proposed device offset percentage for that APC is less than 40 percent.

INPATIENT-ONLY PROCEDURES (page 41516 – 518)

Background

Under the OPSS, there are certain procedures that are deemed “inpatient-only” for which hospitals will not receive an OPSS payment if they are performed in the hospital outpatient department. CMS updates the list periodically, in large part to remove procedures from the list that staff determine can now be safely performed on an outpatient basis.

Proposed Rule

Under the proposed rule, 11 procedures would be taken off the “inpatient-only” list and paid under the OPSS in 2009. The list of procedures proposed to be taken off the “inpatient-only” list is published in Table 35 (page 41518). This table also contains the APC to which the service will be assigned for payment purposes.

CMS relied on recommendations from the public, the APC Advisory Panel, utilization data and review by CMS’s medical advisors to develop this list. In response to the APC Panel’s recommendation during its March 2007 meeting, CMS is seeking input regarding two of the CPT codes proposed for removal from the inpatient list: CPT codes 54535 and 61850.

Although CMS considered removing CPT code 64818 (Sympathectomy, lumbar), at its March 2008 APC Panel meeting, the Panel made no recommendation regarding this code and CMS is not proposing to remove it from the inpatient-only list for CY 2009.

Analysis

AAMC teaching hospitals should review the list in Table 35, in particular to determine the appropriateness of the APCs to which CMS is assigning the previously “inpatient-only” services. Hospitals also should review the list of services that remain on the “inpatient-only” list (Addendum E, pages 42174 - 212) to determine whether any of these can safely be performed in an outpatient setting and, therefore, should be payable under the OPSS.

CHANGES TO THE AMBULATORY SURGICAL CENTERS (ASCs) PAYMENT SYSTEM (pages 41523 – 539)

The proposed rule contains changes for the ASC payment system that would be implemented in CY 2009. CMS is proposing:

- to add approximately nine procedures that are not currently part of the ASC list; these include three procedures for which the American Medical Association’s CPT (Current Procedural Terminology) Editorial Panel has created new codes and descriptors, and six procedures that were previously excluded from payment under the ASC payment system; and

- to add five procedures to the list of office-based procedures (subject to payment at the lesser of the office practice expense payment to the physician or the standard ASC rate), and to update the list of device-intensive procedures and covered ancillary services and their rates, consistent with proposals in the OPSS update.

SUMMARY

Outpatient departments and clinics are critical components of teaching hospitals. The 2009 Medicare outpatient proposed rule makes some important changes to the payment system. These changes could have a significant impact on teaching hospitals' Medicare outpatient payments and decision-making.

If you have any questions regarding the proposed rule or this summary, or have concerns that you would like to discuss for possible inclusion in the Association's comment letter, please contact Diana Mayes, at dmayes@aamc.org, 202-828-0498 or Karen Fisher at kfisher@aamc.org, or 202-862-6140.