

August 3, 2009

AAMC Summary and Analysis

CALENDAR YEAR 2010 MEDICARE OUTPATIENT PPS PROPOSED RULE: PROVISIONS OF INTEREST TO AAMC MEMBERS

On July 20, 2009, the Centers for Medicare and Medicaid Services (CMS or the Agency) published in the Federal Register, its calendar year 2010 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 2010 Payment Rates ...*” [74 Fed. Reg. 35,232]. The proposed rule can be obtained on the AAMC’s web site at: <http://www.aamc.org/advocacy/teachhosp/outptpps/start.htm>. If finalized, these policies will take effect January 1, 2010.

Highlights of the Proposed Rule Include:

- Requirements for "direct supervision" of hospital outpatient therapeutic services furnished in a hospital and in on-campus provider-based departments (PBDs) of a hospital (p. 3-6)
- Payment for separately payable drugs and biologicals at ASP plus four percent (p. 6-13)
- Outpatient Quality Reporting Program Provisions (p. 17-19)
- An almost 24 percent increase in the outlier payment threshold (p. 19-21)

In this rule, CMS is also proposing changes to the Ambulatory Surgical Center (ASC) payment system and CY 2010 payment rates, which also will take effect January 1, 2010. 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 **August 31, 2009**.

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=CMS1224005&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 OPSS 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 35,291 and 35,416)

The proposed rule implements the current law requirement that the OPSS base payment rate (known as the "conversion factor") be increased to reflect the full increase in the hospital inpatient market basket, as published in the FY 2010 inpatient PPS final rule. This increase is 2.1 percent for CY 2010. For hospitals that do not submit quality 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).

For CY 2010, CMS estimates that the proposed changes would result in a 1.9 percent increase in OPSS payments for all hospitals. However, major teaching hospitals would see an overall average increase in OPSS payments of 1.7 percent, compared to a 1.9 percent and a 2.0 percent increase for minor teaching and non-teaching hospitals respectively (see Impact Table 51 on page 35,416).

Analysis

According to CMS's impact analysis (page 35,416), the projected 1.9 percent increase for all providers reflects the proposed 2.1 percent market basket increase, less 0.01 percent for the change in the pass-through estimate between CY 2009 and CY 2010, less 0.08 percent for the difference in estimated outlier payments between CY 2009 (1.08 percent) and CY 2010 (1.0 percent), and less 0.14 percent due to the expiration of the special, non-budget neutral wage index payments made under section 508. The proposed rule does not provide any analyses that explain why the estimated overall increase in payment rates for major teaching hospitals is lower than that of other hospital groups.

PHYSICIAN SUPERVISION (pages 35,362 – 370)

Background

Hospital Outpatient Therapeutic Services

Currently, Medicare pays for outpatient therapeutic hospital services (such as pulmonary and cardiac rehabilitation services) furnished "incident to" a physician's service. (Social Security Act § 1861(s)(2)(B).) Medicare regulations set three basic conditions of payment for these services, which must be: (1) furnished by or under arrangement made by a hospital; (2) as an integral though incidental part of a physician's service; and (3) furnished in the hospital or at a department of a provider, as defined in §413.65(a)(2), that has provided-based status. (42 C.F.R. §410.27(a)(1)(i)-(iii)). In 2009, CMS published what it described as a "restatement and clarification" of existing policy, saying that hospital outpatient therapeutic services are to be provided under the direct supervision of physicians in the hospital and in all provider-based departments (PBDs) of the hospital, specifically both on-campus and off-campus departments. Until the publication of the "clarification," most hospitals understood that the CMS policy for provider-based on-campus departments did not require direct physician supervision.

Hospital Outpatient Diagnostic Services

According to statute, Medicare makes payment for diagnostic services furnished at PBDs of hospitals "only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in §§410.32(b)(3)(i) through (iii)."

Since the April 2000 OPFS final rule, CMS pays for diagnostic services furnished at PBDs of hospitals using the same supervision requirements as those used for physician supervision of diagnostic tests payable under the Medicare Physician Fee Schedule (MPFS) that was set forth in the CY 1998 MPFS final rule (62 FR 59,048). For diagnostic services not listed in the MPFS file, Medicare contractors, in consultation with their Medicare directors, define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary.

Proposed Rule

Hospital Outpatient Therapeutic Services

In response to the many concerns about the change in policy related to supervision of therapeutic services in an on-campus provider-based department, CMS has proposed the following changes for CY 2010:

- Allowing nonphysician practitioners (NPP), such as physician assistants, nurse practitioners, clinical nurse specialists, and certified midwives, to provide direct supervision of all hospital outpatient therapeutic services that are within their scope of practice or hospital-granted privileges, provided that they meet all additional requirements, including any collaboration or supervision requirements. The Agency would add new §410.27 (a)(1)(iv) to reflect these changes.
- “Refining” the definition of direct supervision of hospital outpatient therapeutic services furnished in a hospital and in on-campus PBDs of a hospital.
 - CMS proposes that for services furnished on a hospital’s main campus, the supervisory physician or nonphysician practitioner must be present on the same campus, in the hospital or other on-campus PBD of the hospital and be immediately available to furnish assistance and direction throughout the performance of the procedure.
 - “In the hospital” will mean in the main building(s) of a hospital that are under the ownership, financial, and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital’s CMS Certification Number (CCN). CMS states that “the supervisory physician or nonphysician practitioner could not be immediately available while, for example, performing another procedure or service that he or she could not interrupt.” Additionally, the physician or nonphysician practitioner could not be so physically far away on the main campus that he or she could not intervene right away. It is not sufficient for the physician or nonphysician practitioner to just respond to an emergency. He/she “must be prepared to step in and perform the service.”

CMS also briefly addresses the issue of supervision at off-campus remote locations. The Agency “continue[s] to believe that it would be inappropriate to allow one physician or nonphysician practitioner to supervise all services being provided in all PBDs at a particular off-campus remote location.”

Hospital Outpatient Diagnostic Services

CMS is not proposing to allow nonphysician practitioners, other than clinical psychologists, to provide the supervision of diagnostic tests furnished to hospital outpatients. Clinical psychologists are allowed to supervise only diagnostic psychological and neuropsychological testing services when they or another practicing psychologist furnish the services or when the services are furnished under the general supervision of a physician or clinical psychologist.

The Agency is proposing to require that all hospital outpatient diagnostic services that are provided directly or under arrangement, whether provided in the main buildings of the hospital, in a PBD, or at a nonhospital location, follow the physician supervision requirements for individual tests as listed in the MPFS Relative Value File.

Under the proposed rule, the definition for direct supervision of diagnostic services that are provided directly or under arrangement – whether provided in the main hospital buildings or on-campus in a PBD, in an off-campus PBD or at a nonhospital site – would be the same as the definition for therapeutic services. That is, for services provided on-campus, the physician would need to be present on the same campus, in the hospital or the on-campus PBD of a hospital, as defined in §413.65, and immediately available to furnish assistance and direction throughout the performance of the procedure (this change would be codified in proposed §410.28(e)(1)). For services provided in an off-campus PBD, the physician must be present in the off-campus PBD, as defined in §413.65 and immediately available to furnish assistance and direction throughout the performance of the procedure (this change would be codified in proposed §410.28(e)(2)). This does not mean that the physician must be in the room when the diagnostic procedure is being performed.

Similarly, the definition of “in the hospital” as defined in proposed §410.27(g) would apply.

Analysis

Hospital Outpatient Therapeutic Services

As a result of concerns expressed by the hospital and physician community, including the AAMC, CMS proposes two important changes to the physician supervision requirements. First, is to allow certain nonphysician practitioners to directly supervise all hospital therapeutic services that they perform under state law and scope of practice or hospital-granted privileges. Second, is to change the requirements for “direct supervision” of hospital outpatient therapeutic services. The proposal appears to be more flexible. However, the requirements that CMS is suggesting, relating to having a physician or NPP “immediately available” may be challenging to meet. Those requirements appear to prevent a physician from engaging in most types of work that would result in performing billable services, as they could only supervise if they were engaged in work that could be immediately interrupted. Additionally, there are physician offices and other entities that may be located in the main building of the hospital but because they are operated independently of the hospital, they would not be included in the proposed definition of “in the hospital.” However, these offices are located on the campus of the hospital and the physicians could be immediately available to furnish assistance and direction throughout the performance of the procedure. If CMS finalizes the rule as proposed, hospitals are likely to face the challenge of finding sufficient physicians and NPPs to comply with the requirements with the possible result that beneficiaries will find that their access to these services is limited.

The second concern is related to CMS’s decision to implement the proposed policies starting in CY 2010, rather than make them retroactive. In spite of the confusion among the hospital and physician community that CMS acknowledges, the Agency states “We have not instructed contractors to delay initiation of enforcement actions or to discontinue pursuing pending enforcement actions regarding the physician supervision of hospital outpatient services.”

The AAMC will strongly urge CMS to provide a more flexible definition of “immediately available” and to instruct contractors to delay initiation of enforcement actions or to discontinue pursuing pending enforcement actions regarding the physician supervision of hospital outpatient services.

OPPS PAYMENTS FOR CURRENT DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS (pages 35,318 – 336)

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. In CY 2009, 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.

Because biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body function as implantable devices, for CY 2009, the Agency began packaging the HCPCS codes for these products when used as implantable devices into the procedures with which biological was reported in the claims data. According to CMS, implantable biologicals may be used in place of implantable non-biological devices whose costs are already accounted for in the payment for the APC for the associated surgical procedure. The Agency states that continuing to provide separate payment for these products could result in providing duplicate device payment, both through the packaged non-biological device cost included in the surgical procedure’s payment and the separate biological payment.

Separately Payable Drugs and Biologicals (pages 35,324 – 336)

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 2009, separately payable drugs and biologicals are reimbursed at ASP plus four percent, a one percent lower payment rate than the payment rate hospitals received in CY 2008. It also is two percent lower than the physician office setting payment rate of ASP plus six percent.

Currently, claims data for hospitals that participate in the 340B program are included in the calculation of payment for drugs and biologicals. Hospitals that participate in the program are generally hospitals that serve a disproportionate share of low-income patients and receive disproportionate share payments under the inpatient prospective payment system (IPPS). These hospitals generally acquire outpatient drugs and biologicals at prices that are substantially below ASP because the 340B program requires drug manufacturers to provide outpatient drugs to eligible entities at a reduced price. Manufacturers do not submit these reduced price sales to Medicare when they submit the ASP data.

For drugs and biologicals for which CMS does not have ASP data, the Agency uses the mean costs from the CY 2007 hospital claims data as their payment rates for CY 2009.

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 radiopharmaceutical 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. Because CMS considers that all diagnostic

radiopharmaceuticals are intended to be used with a diagnostic nuclear medicine procedure, the Agency began packaging these products with the diagnostic nuclear medicine procedure with which they are performed. For CY 2009, the Agency continues to package 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.

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 beginning in CY 2006, claims data (which were used to calculate payment rates for radiopharmaceuticals for CY 2008) reflect both the radiopharmaceutical charge and the associated overhead charges. As a result, CMS finalized a prospective payment policy for therapeutic radiopharmaceuticals for CY 2008. However, the policy was not implemented on January 1, 2008, because the Medicare, Medicaid, and SCHIP Extension Act of 2007, which was enacted on December 29, 2007, prior to the implementation of the CY 2008 rule, required that CMS pay for therapeutic radiopharmaceuticals for the period of January 1, 2008 through June 30, 2008 at hospitals' charges adjusted to costs. The prospective payment rates were supposed to take effect July 1, 2008 (see Change Request (CR) 5912) and for CY 2009. However, the Agency did not implement the proposed payment rates for the second half of CY 2008, because the Medicare Improvements for Patients and Providers Act of 2008, which became law on July 15, 2008, extended the cost-based methodology for determining payment for therapeutic radiopharmaceuticals until January 1, 2010. The law also prevented CMS from finalizing its proposal for a prospective payment for therapeutic radiopharmaceuticals in CY 2009.

Proposed Rule

The proposed packaging threshold for CY 2010 would equal \$65. Drugs, nonimplantable biologicals and therapeutic radiopharmaceuticals whose cost per day is less than \$65 would be packaged with the procedures with which they are billed and those whose cost exceeds \$65 would be paid separately.

Diagnostic radiopharmaceuticals and implantable biologicals would continue to be packaged into the procedure that they are associated with, regardless of their costs. CMS would continue to instruct hospitals to not bill separately for the HCPCS codes for implantable biologicals when used as implantable devices.

Separately Payable Drugs, Biologicals

Proposed Rule

CMS used manufacturer-submitted ASP data from the fourth quarter of CY 2008, the most current ASP data available, as well as mean costs derived from the CY 2008 hospital claims data, to calculate payment rates for drugs and nonimplantable biologicals in the

proposed rule. However, since new data will become available when the final rule is published, CMS proposes to use ASP data from the first quarter of CY 2009, as well as mean costs derived from the CY 2008 updated hospital claims data, to set the payment rates for drugs and biologicals that will be published in the CY 2010 OPPS final rule.

For CY 2010, CMS proposes a payment rate of **ASP plus four percent** to cover both the acquisition and handling costs for drugs and biologicals. Although this is the same payment rate as that used in CY 2009, CMS determined it by using a new methodology than the one used since CY 2006. Under the prior methodology, the acquisition and pharmacy overhead cost for separately payable drugs and biologicals would be equal to a payment of ASP minus two percent. Recognizing that its standard methodology for estimating the acquisition and overhead costs of separately payable drugs and biologicals underestimates their acquisition and overhead costs, the Agency is proposing to redistribute \$150 million from packaged drugs and biologicals to separately payable drugs and biologicals to provide an adjustment for the pharmacy overhead costs of these items. This represents between one-third and one-half of the difference between the aggregate claims cost for packaged drugs and biologicals and ASP dollars for these products.

Under the proposed rule, claims data for hospitals that participate in the 340B program would continue to be included in the calculation of payment for drugs and biologicals. Reimbursement for drugs and biologicals provided by 340B hospitals would be at the same rate as that of separately payable drugs and biologicals provided by hospitals that do not participate in the 340B program.

For drugs and biologicals for which ASP data are not available, CMS is proposing to use their mean costs from the CY 2008 hospital claims data as their payment rate.

Analysis

CMS's current methodology for estimating the acquisition and pharmacy overhead costs for separately payable drugs and biologicals is to compare the estimated aggregate cost of separately payable drugs and biologicals in the claims data to the estimated aggregate ASP dollars for these products, using the ASP as a proxy for average acquisition and pharmacy overhead cost. Based on CMS's current methodology, separately payable drugs and biologicals would be reimbursed at ASP minus two percent.

However, CMS recognizes that due to the combined effects of charge compression and the Agency's choice of a drug packaging threshold, the current allocation of pharmacy overhead costs to packaged or separately payable drugs and biologicals does not reflect an appropriate allocation of overhead costs. Charge compression is the practice of applying a lower charge markup to higher-cost services and a higher charge markup to lower-cost services. As a result, some of the pharmacy costs that should be associated with the separately payable drugs are being included with the packaged drugs, thus resulting in an estimated cost calculation for separately payable drugs that is significantly lower than it should be. The charge compression problem is exacerbated as the packaging threshold

increases because the cost value for the remaining high cost separately payable drugs decreases, even though there is no change in the overhead costs for these items.

According to CMS, under the current methodology, the estimated aggregate cost of packaged drugs and biologicals, including acquisition and pharmacy overhead costs is ASP plus 247 percent, while the estimated cost for all drugs and biologicals including acquisition and pharmacy overhead costs is equivalent to ASP plus 13 percent. As a result, the Agency proposes to redistribute some portion (\$150 million), but not all, of the \$395 million in total overhead cost to separately payable drugs and biologicals. This represents a 27 percent reduction in packaged drug and biological costs.

The Agency is proposing to redistribute between one-third and one-half of the difference between the total claims cost for packaged drugs and biologicals and ASP dollars for these products, rather than the entire difference (\$395 million) because the Agency believes that the “indirect” overhead cost alone for an inexpensive drug or biological could be far in excess of the ASP for that inexpensive drug. Indirect costs are those costs that are shared by all hospital items and services and include administrative and general costs, capital costs, staff benefits, and other facility costs. Direct costs are pharmacy overhead costs that include handling, preparation, and distribution of drugs and biologicals. These pharmacy overhead direct costs vary, sometimes considerably, depending upon the drug being furnished.

CMS is not proposing a pharmacy stakeholders’ approach submitted to CMS as part of the stakeholders’ comments on the CY 2009 OPDS, but uses some of the elements of that approach to determine the appropriate amount of payment redistribution. This group consists of some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations. The stakeholders’ approach would pay for separately payable drugs and biologicals at ASP plus six percent. This amount would include the acquisition costs with some of the pharmacy overhead costs for these products. Rather than estimating the cost of packaged drugs and biologicals based on claims data, CMS would substitute ASP plus six percent for the cost of all packaged drugs and biologicals on procedure claims. The difference between the estimated aggregate costs for all drugs derived from claims data and the cost of packaged drugs and biologicals at ASP plus six percent would be used to create a pool of money that would be distributed to separately payable drugs and biologicals to account for pharmacy overhead costs associated with these products. This pool of funds would be used to allocate a separate overhead payment for each separately payable drug or biological at one of three different levels, depending on the stakeholders’ assessment of the complexity of pharmacy handling associated with each specific drug or biological.

The Agency’s rationale for not adopting the stakeholders’ proposal is twofold. First, the stakeholders’ approach would establish ASP plus six percent as the cost of packaged drugs and biologicals, including all pharmacy overhead costs. However, as noted above, CMS believes that the indirect overhead cost alone for an inexpensive drug or biological could be far in excess of the ASP for that inexpensive drug, which would make substituting ASP plus six percent for the cost of packaged drugs and biologicals inappropriate. Secondly, the Agency believes that a methodology that would provide separate pharmacy overhead

payment for each separately payable drug and biological based on its pharmacy complexity is akin to unbundling payment for these products and not in line with a prospective payment system that provides payment for groups of services rather than individual services.

Although CMS did not adopt the stakeholders' approach, it did use information provided by the pharmacy stakeholders and MedPAC in its June 2005 Report to Congress, to estimate the appropriate portion of the pharmacy overhead cost currently associated with packaged drugs and biologicals that may need to be allocated to separately payable drugs and biologicals. The Agency did two similar analyses, one based on MedPAC information and the other based on the pharmacy stakeholders' information to see whether it would arrive to the same result (for details on the methodology see pages 35,330- 331). Using relative overhead weights based on MedPAC's information, the value of packaged drugs and biologicals drops from ASP plus 247 percent to ASP plus 144 percent, while the payment rate of separately payable drugs and biologicals increases from ASP minus two percent to ASP plus four percent. Similarly, using weights based on the pharmacy stakeholders' approach, the value of packaged drugs and biologicals would be ASP plus 151 percent, while the payment rate for separately payable drugs and biologicals would be ASP plus four percent. Since both approaches result in a payment rate for separately payable drugs and biologicals that equals ASP plus four percent, CMS concludes its proposal represents a reasonable aggregate adjustment for the pharmacy overhead cost of these products compared to the current methodology.

Although this proposal seems to be an improvement in CMS's methodology for estimating the acquisition and pharmacy overhead cost for separately payable drugs and biologicals, in that, it attempts to address the issue of charge compression, we are concerned that CMS's methodology may still underestimate these costs. For example, one concern is related to the Agency's decision not to propose the APC Panel's recommendation to exclude data from hospitals that participate in the 340B program. Since 340B hospitals receive drugs and biologicals at discounted rates while their sales are excluded from the ASP calculation, incorporating data from these hospitals results in an underestimation of aggregate costs of drugs and biologicals. Thus, when CMS compares aggregate costs to ASP it results in an ASP-based rate that is too low.

We are interested in your comments or insight with regard to whether CMS's proposed methodology and payment rate for separately payable drugs and biologicals would indeed more accurately reflect hospital acquisition and pharmacy overhead costs for these items.

Therapeutic Radiopharmaceuticals

Proposed Rule

For CY 2010, CMS is proposing to provide payment for separately payable therapeutic radiopharmaceuticals for which CMS has ASP data at ASP plus four percent. If ASP information is not available, CMS is proposing that payment would be based upon mean unit cost from hospital claims data.

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, 2010, manufacturers would need to submit ASP data no later than November 1, 2009. 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 2008 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 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, and again in the CY 2009 proposed 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. In the CY 2008 final rule, 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 OPPIs 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.” According to CMS,

comments on CY 2009 proposed rule were supportive of the proposal to use the ASP methodology to set payment rates that would cover the average acquisition cost of radiopharmaceuticals and their associated overhead costs.

Drugs, biologicals and radiopharmaceuticals that have HCPCS codes, but no claims data (pages 35,336 – 337)

Background

For CY 2008 and CY 2009, CMS finalized a policy to pay for new drugs and biologicals that have HCPCS codes, but no hospitals claims data at a rate that is equivalent to the payment rate received by 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 makes payment at 95 percent of the product's most recent average wholesale price (AWP). Under the CY 2008 and CY 2009 policy, new therapeutic radiopharmaceuticals are paid at charges adjusted to costs. Thus, for CY 2009, new drugs and biologicals with HCPCS codes but no hospital claims data are paid at ASP plus four percent.

Proposed Rule

For CY 2010, CMS is proposing to reimburse new drugs, non-implantable biologicals and therapeutic radiopharmaceuticals that have HCPCS codes, but no hospitals claims data at the same rate as provided for separately payable drugs, non-implantable biologicals and therapeutic radiopharmaceuticals with claims data (ASP plus four percent).

In the absence of ASP data, CMS is proposing to base payment rate for these items on the WAC for these products. If the WAC are also unavailable, the Agency would make payment at 95 percent of the product's most recent AWP.

For the eight drugs and biologicals (Table 31 at page 35,337) that were payable in CY 2008, but for which CMS doesn't have CY 2008 claims data and any other pricing information for the ASP methodology, the Agency proposes to change their status indicator to "E" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) because they are not currently sold or have been identified as obsolete. CMS would provide separate payment for these items if pricing information reflecting recent sales become available in CY 2010 for the ASP methodology.

TRANSITIONAL PASS-THROUGH PAYMENTS (pages 35,305 – 306), (pages 35,308 – 318) and (pages 35,338 – 340)

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.

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. In 2006, approximately 190 of the most commonly provided drugs in the physicians’ office setting, were covered under the Part B drug CAP¹. For the other drugs and biologicals with pass-through status – that were not part of the Part B drug CAP – CMS has been basing 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.

In the CY 2009 OPSS final rule, CMS suspended the Part B drug CAP program, and no Part B drug is paid at CAP rates in CY 2009. All of the drugs and biologicals with pass-through status are currently paid at ASP plus six percent.

A. Pass-through Payments for New Devices (pages 35,305 – 306)

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.

Pass-through payment for a category of devices is made at the hospital’s charge for the device adjusted to cost by application of the hospital’s CCR.

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. The device APC offset amounts also are used to

¹ 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.

evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices.

Proposed rule

For CY 2010, 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 2010, 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 35,308 – 318)

Proposed rule

Under the proposed rule, pass-through status for 6 drugs and biologicals would expire starting in CY 2010 (Table 21 at page 35,310). Pass-through status for 31 drugs and biologicals (Table 22 at page 35,310-311) would continue in CY 2010. There are no radiopharmaceuticals that are eligible for pass-through payment at this time. CMS would continue to pay for pass-through drugs and biologicals with pass-through status at ASP plus six percent.

Pass-Through Payment Eligibility Period for New Drugs and Biologicals

Proposed Rule

CMS is proposing to change the start date of the pass-through payment eligibility period for a drug or biological, from the first date on which pass-through payment is made to the date of the first sale for a drug or biological in the U.S. following FDA approval. The proposed rule would also end pass-through status on a quarterly basis rather than the current annual basis. That is, the Agency would make the last date of the period of pass-through payment be the last day of the calendar quarter that preceded the pass-through payment eligibility period expiration date. Currently pass-through status of drugs and biologicals expires at the end of the calendar year preceding the year of the applicable OPPS update.

The Agency is not proposing to change its policy for determining the packaging status of a drug or biological after the expiration of the period of pass-through status. That is, packaging status would still be determined on a calendar basis through the annual OPPS rulemaking process. Specifically, even if the pass-through status of a drug or biological ends in a given year's calendar quarter, CMS would make separate payment for those drugs and biologicals through the end of the calendar year, at the same rate as that of separately payable drugs and biologicals without pass-through status, namely ASP plus four percent. However, because contrast agents and diagnostic radiopharmaceuticals are always

packaged regardless of their cost, payment for these items will be packaged as soon as their pass-through status expires.

Analysis

The proposed changes to the pass-through payment eligibility period may begin well before application is made and pass-through status is approved. This could result in a shorter period of pass-through payment for some drugs and biologicals than would otherwise be under the current methodology (for a few examples, see page 35,316).

Implantable biologicals

Proposed Rule

For CY 2010, CMS is proposing that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or orifice) be the device pass-through process and payment methodology (see Pass-Through Payment for New Devices). Since the device pass-through application and evaluation are different from the ones for drugs and biologicals with pass-through status,² implantable biologicals would no longer be eligible to submit biological pass-through applications. Instead hospitals would need to use the pass-through application process for devices.

Furthermore, implantable biologicals with pass-through status will not be reimbursed at ASP plus six percent, which is the payment rate for drugs and non-implantable biologicals with pass-through status, but rather at hospital's charges adjusted to cost, in the same manner as devices with pass-through status are reimbursed. In addition, just as it does for devices with pass-through status, CMS would deduct from the pass-through payments for the implantable biological the offset amount equal to the portion of the APC payment amount associated with the device that the implantable biological is replacing.

Implantable biologicals that have pass-through status prior to January 1, 2010, would continue to be considered pass-through biologicals for the duration of their period of pass-through payment.

Analysis

Currently, the pass-through evaluation process and pass-through payment methodology for implantable biologicals is the same as that of non-implantable biologicals.

Because biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body function as implantable devices, since CY 2009, CMS began treating the non-pass-through implantable biologicals as implantable devices. Thus, CMS began packaging payment of implantable biologicals into payment for the associated

² The statutory provisions are not the same for all items that may receive pass-through status.

surgical procedure (see OPSS Payment for Current Drugs, Biologicals and Radiopharmaceuticals).

Since the non-pass-through implantable biological and non-biological devices share similar payment methodologies, have overlapping and sometimes identical clinical uses, and are treated in the same manner by the FDA regulations³, CMS believes that the proposed policy of applying the device pass-through process to both biological and non-biological implantable devices is appropriate.

According to the Agency, the proposed policy also eliminates CMS's concern that an implantable biological is eligible for OPSS pass-through payment twice: once for a period of device pass-through payment then for a period of drug or biological pass-through payment.

C. Pass-Through Payment Pool (pages 35,338 – 340)

Pursuant to current law, CMS is authorized to spend up to two percent of total OPSS payments for pass-through payments.⁴ CMS estimates however, that in CY 2010, only 0.12 percent of total OPSS payments will be needed for pass-through payments. This figure includes CMS's estimates for the device categories (including implantable biologicals) that may become eligible for pass-through status after the proposed rule was published and before the beginning of CY 2011 (estimated at \$10.0 million); projections for the 31 drugs and biologicals eligible for pass-through payments in CY 2010 (estimated at \$8.9 million) as well as estimates for any drugs, biologicals and radiopharmaceutical that may become eligible for pass-through payments after the proposed rule was published and before the beginning of CY 2011 (estimated at \$19.1 million in CY 2010). Accordingly, the OPSS conversion factor will be reduced by only 0.12 percent.

REPORTING QUALITY DATA FOR ANNUAL PAYMENT RATE UPDATES (HOP QDRP) (pages 35,394 – 405)

Measures

For the CY 2011 payment determination, CMS has not proposed any additional measures. Therefore, the measures required for CY 2010 would remain the same for CY 2011. CMS has provided a list of measures that may be considered for CY 2012 (see page 35,398).

³ The FDA regulations treat the non-pass-through implantable biologicals as devices.

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 2010, 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 2010 (page 35,338).

Validation

CMS is proposing to implement a new validation program similar to what was proposed for the inpatient program. The new program would be fully implemented for CY 2012, but using CY 2011 as a test year. The results of the validation for the initial year would have no impact on the CY 2011 payment update. However, the validation results for CY 2012 would impact the payment update if the validation results did not meet the required threshold.

For CY 2011, CMS would randomly select 7,300 cases from all of the cases submitted for the OPPTS program. Hospitals with selected cases would then be contacted to provide the appropriate medical record documentation. Once the documentation has been received, the CMS contractor would re-abstract the data from the data warehouse and compare that to the data submitted by the hospital. A percent agreement would then be calculated and shared with the hospital. Again, the results of the comparison would have no impact on the CY 2011 payment and would only serve to educate hospitals on how the validation program would operate.

For CY 2012, CMS is proposing to randomly select 800 hospitals for validation. For each hospital that is selected, a total of 12 cases per quarter or a total of 48 cases for the year would be validated. The process for validation would be the same as for CY 2011. However hospitals would now need to pass a reliability score of 90% in order to receive their full update. The reliability score for the outpatient validation is higher than what is currently required for the inpatient program (80%) based on the assumption that hospitals would have an easier time in scoring higher on the measure level matching they are conducting for the outpatient program as opposed to the data element approach used for the inpatient program. For example, in the outpatient validation process a hospital does not need to have the underlying data elements match that is in the data warehouse, but rather have the same overall result for the measure as compared to what is in the data warehouse.

As a result of only selecting 800 hospitals per year for validation, CMS is looking for additional criteria for 2012 – such as abnormal data patterns or not being previously selected for validation for at least two years – to flag hospitals for validation after CY 2012.

Public Reporting

CMS is proposing to publicly report the data from the hospital outpatient program beginning with the third quarter of CY 2008 (July – September 2008) whether or not the data have been validated.

Reporting of ASC Quality Data

CMS is proposing to defer the submission and public reporting of quality data from Ambulatory Surgery Centers to future rulemakings. They are soliciting input on the proposed deferral.

Health Care Associated Conditions (HAC) (pages 35,405 – 407)

CMS has proposed to not expand the current hospital acquired conditions program to the hospital outpatient setting in this rulemaking. While CMS is still committed to addressing HACs in the

hospital outpatient setting, the Agency realizes there are significant operational as well as structural challenges to implementing such a program at this time. CMS received significant input from the field through comments on last year's rule as well as during a listening session for HACs in which commenters urged CMS to evaluate the inpatient program prior to expanding to the outpatient setting. As a result, a study is being conducted on the impact of the HAC program and the present on admission (POA) reporting for the inpatient setting. The results of this report will be used to inform future decisions regarding the expansion to the outpatient setting.

CHANGES TO OPPTS OUTLIER POLICIES (pages 35,295 – 297)

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 OPPTS. 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 2009, CMS maintained the total outlier payments at one percent of the aggregate total payments.

Outlier eligibility is determined at the individual OPPTS 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 2009, 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 \$1,800 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 cost-to-charge ratios (CCRs) to reflect the 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 2007 claims – the data used to set payment rates for CY 2009 – by the same inflation factor used to estimate the IPPS fixed-dollar threshold as estimated in the FY 2009 IPPS final rule.

In the CY 2009 OPPTS final rule, the Agency finalized its proposal to reconcile hospital outlier payments at cost report settlement for services furnished during cost reporting periods beginning in CY 2009. This reconciliation process is similar to that implemented by the IPPS in FY 2003 (63 Fed. Reg. at 34,494), and according to CMS, it ensures more accurate outlier payments for those facilities whose CCRs fluctuate significantly relative to the CCRs of other facilities, and who receive a significant amount of outlier payments.

Under the reconciliation process, CMS sets OPPS outlier reconciliation thresholds, which include a measure of an acceptable percent change in a hospital's CCR and an amount of outlier payment involved. Outlier reconciliation thresholds, which are provided in section 10.7.2.1 of Chapter 4 of the Medicare Claims Processing Manual (Pub. 100-4), are reevaluated annually and modified if necessary. When the cost report is settled, reconciliation of outlier payments is based on the overall CCR, calculated as the overall ratio of costs and charges computed from the cost report at the time the cost report coinciding with the service dates is settled.

In the CY 2009 final rule, CMS also finalized a proposal 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 applies a downward adjustment to account for the value of the money for the time period in which the money was inappropriately held by the hospital. An upward adjustment applies to hospitals that received less in outlier payments (before the reconciliation) than they were supposed to receive.

For costs reporting periods beginning on January 1, 2009, Medicare contractors are identifying cost reports that require outlier reconciliation as a component of the cost report settlement. CMS is still in the process of developing a method for reexamining claims to calculate the change in total outlier payments in order to reconcile outlier payments for these cost reports.

Proposed Rule

For CY 2010, CMS is again proposing to allocate only one percent of aggregate total payments for outlier payments. CMS would also set aside 0.02 percent of total outlier payments to Community Mental Health Centers (CMHCs) for partial hospitalization outliers.

CMS proposes to increase the fixed-dollar threshold by \$425, an almost 24 percent increase from CY 2009 (from \$1,800 to \$2,225), while keeping the multiplier threshold at its current level of 1.75, to meet the one percent threshold. Thus, for CY 2010, 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 \$2,225 fixed-dollar threshold. The payment percentage would remain the same – 50 percent.

Analysis

CMS uses a similar methodology to calculate the fixed-dollar outlier threshold for the OPPS to the one used in calculating the fixed-dollar outlier threshold in the IPPS. For the FY 2010 IPPS proposed rule, the AAMC along with the AHA and FAH, asked Vaida Health Data Consultants (Vaida) to review the methodology and provide its view about how the methodology could be improved. In its review, Vaida noted that the current methodology overestimates the outlier fixed-dollar threshold for a few reasons, two of which apply to both the OPPS and the IPPS outlier threshold determination. Vaida also makes two recommendations that would address these two issues and would lead to a more accurate estimation of the outlier fixed-dollar threshold. The first is to recognize that hospitals have different fiscal year ends and, rather than project the CCRs for all hospitals for a period of one year, to base the CCRs for all hospitals over a period of two years.

Such a change would acknowledge that hospitals have different fiscal year ends and would utilize their most current CCR as it becomes available. The second recommendation is to use a recent historical industry-wide average rate of change of CCRs as the projection factor rather than utilizing the relationship between actual costs and the hospital market basket and assuming that the rate of change is constant over time. The AAMC has urged CMS to adopt these recommendations for the IPPS and will urge the Agency to do the same for the OPSS outlier threshold determination.

In response to comments made by the AAMC and others, CMS began publishing total outlier payments as a percent of total expenditures. The Agency's current estimate of CY 2008 total outlier payments as a percent of total CY 2008 payments is 1.2 percent. For CY 2009, CMS estimates that outlier payments would be approximately 1.08 percent of total CY 2009 OPSS payments.

PARTIAL HOSPITALIZATION SERVICES (pages 35,354 – 356)

The partial hospitalization program (PHP) is an outpatient program for psychiatric services provided to patients in lieu of inpatient care. According to CMS, the PHP is a highly structured and clinically-intensive program, usually lasting most of the day.

Since August 1, 2000, CMS has paid for partial hospitalization services provided by both hospital outpatient departments and community mental health centers (CMHCs), based on the same PHP APC rate. Because the Agency considers a day of care as the unit that defines partial hospitalization services, payment for the PHP APC was determined based on a per diem methodology. Specifically, CMS has calculated median costs for the PHP APC payment rate by combining hospital-based and CMHC median per-diem costs derived from both hospital and CMHCs claims data.

Since CY 2006, CMS's analyses of hospital and CMHC data have shown a much lower combined hospital-based and CMHC median per diem cost than what CMS was expecting. Because CMS was concerned that these rates did not accurately reflect the costs of partial hospitalization services, and to ensure access to this needed service to vulnerable populations, the Agency reduced the PHP rates by less than the decline in the hospital-based and CMHC median per diem cost. CMS, however, continued to study the causes for the low per diem median cost for PHP.

Beginning with the CY 2008 rulemaking cycle, CMS began exploring the possibility that the number of units of service provided in a day of care may be a reason for the low median cost for PHP. Based on the Agency's analysis of the CY 2006 and CY 2007 claims data, both hospitals and CMHCs were providing fewer than four units of service per day for a significant number of days.

CMS noted that it expected the PHP to be a clinically-intensive program consisting of days with five or six services and that days with three services would be provided only in limited circumstances, such as when a patient is transitioning towards discharge or would be required to leave the PHP early for the day due to an unexpected medical appointment.

CMS believes that the lower than expected per diem median cost for PHP was due to the relatively high proportion of days with fewer than four units of services.

Thus, to distinguish between the costs associated with partial hospitalization services provided during days with four or more services and those with three services, for CY 2009, CMS finalized its proposal to create two separate APC payment rates for PHP – one for days with three services (APC 0172) and one for days with four or more services (APC 0173). In response to comments from the AAMC and others, CMS also rescinded its proposal to continue to set payment rates for the partial hospitalization program (PHP) services provided in hospitals based on combined hospital and community mental health centers (CMHCs) data. Instead, payment rates for the two new PHP APCs are based on hospital data only. Both hospitals and CMHCs are paid the same two APC per diem payment rates.

Proposed Rule

For CY 2010, CMS is proposing to continue to use only hospital-based PHP data to develop the two PHP APC per diem payment rates: one for days with three units of service (APC 0172, paid at \$149, down from \$157) and one for days with four or more units of service (APC 0173, paid at \$213, up from \$200).

Analysis

Because there is a two-year delay between data collection and rulemaking, CMS will not have access to data reflecting the changes made in CY 2009 until next year's rulemaking process. As a result, the Agency is concerned about further reducing the payment rates without knowing the impact of the policy. However, because currently CMS uses only hospital data to develop rates for both hospitals and CMHCs and the Agency believes that both types of providers should have their data utilized in the development of the payment rates, CMS is requesting comments about the possibility of again using both CMHC and hospital-based PHP data to develop PHP payment rates for CY 2010.

EVALUATION AND MANAGEMENT CODES (E/M) (pages 35,349 – 354)

Background

Since the implementation of the OPPS, 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, CMS paid hospitals 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 hospitals provide 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 is currently no consistent coding methodology 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 both on public comments and on 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 a day, 7 days a week), but incurs obligations under the Emergency Medical Treatment and Labor Act (EMTALA), is referred to as a Type B emergency department (see page 35,351).

In the past, CMS had not been able to distinguish, for payment purposes, between hospital resource costs associated with services provided during 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 a day, 7 days a week. However, CMS recognized that Type B emergency department visit costs may be greater than the costs hospitals incur for clinic visits, because they are more likely to treat patients that are similar clinically and in terms of resource use to those patients treated in Type A emergency departments. Still, because they are not open 24 hours a day, CMS was uncertain whether Type B emergency department 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. 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 visit APC payment level.

For CY 2009, CMS created, for each of the five G-codes representing a Type B emergency department, four new APCs corresponding to the first four levels of G-codes that represent the first four levels of Type B visits. Payment for each Type B emergency room visit APC is higher than payment for the corresponding clinic visit APC and lower than payment for the corresponding Type A emergency room visit APC. Payment for level 5 Type B emergency room visits is paid at the same rate and through the same APC as payment for level 5 Type A emergency department visits.

Proposed Rule

Visit Reporting Guidelines

The Agency is not proposing national guidelines for CY 2010. 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

CMS is not proposing any changes with respect to payments for clinic visits.

For Type B emergency department visits, CMS is proposing to create a new APC entitled “Level 5 Type B Emergency Visits” and to pay level 5 Type B emergency department visits through this new APC. Although CMS initially found, using CY 2007 claims data, that level 5 visits for Type A and Type B emergency departments had similar hospital resource costs, the Agency has now modified this conclusion based on new cost data. Using cost data from CY 2008, CMS now concludes that median costs are lower for level 5 Type B compared to Type A emergency department visits. Therefore, level 5 Type B emergency room visits will now be paid at a lower rate than level 5 Type A emergency room visits. To distinguish between the two level 5 APCs, CMS is also proposing to rename the current level 5 Type A emergency visit APC to incorporate “Type A” in the title.

Analysis

Visit Reporting Guidelines

To determine whether the internal guidelines 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, 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 2010 according to their own internal guidelines.

Payment for emergency department visits

According to CMS's analyses, new CY 2008 claims data indicate that the median costs of Type B emergency department visits are less than the median costs of Type A emergency department visits across all five levels. CMS will, accordingly, make lower payments for Type B emergency department visits than for Type A visits across all levels (see Table 35 on page 35,351).

COMPOSITE APCs (pages 35,278 – 286)

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).

In CY 2009, CMS created five multiple imaging composite APCs for the following three modalities: ultrasound, CT and CTA, and MRI and MRA. Specifically, the Agency created 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 created a separate composite APC for the ultrasound modality. Thus, the five multiple imaging composite APCs are: 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).

For CY 2009, CMS is basing the composite APC payment amount entirely on median costs derived empirically from CY 2007 OPDS claims for multiple imaging services provided in a single session and Medicare cost report data. The composite APC amount includes payment for packaged services furnished on the same date of service as the imaging services included in the composite APC.

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 receives payment for the with contrast composite APC.

If a hospital performs imaging procedures with HCPCS codes from different imaging families, then the hospital receives payment based on the “sole service” (when only one imaging service was performed during a single session) imaging APC to which they are assigned.

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

Proposed Rule

In response to comments to the CY 2009 proposed rule urging CMS to not implement additional composite APCs until adequate data are available to evaluate the composite APCs effectiveness and impact on utilization and payment, the Agency is not proposing any new composite APCs for CY 2010. However, the Agency will continue its composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services.

The proposed rates for the five multiple imaging composite APCs are based on median costs calculated from the partial year CY 2008 claims with more than one procedure within the same family on a single date of service.

Table 10 (page 35,284) 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 in a single date of service.

Analysis

Although CMS believes that there are efficiencies resulting from performing multiple imaging procedures in a single session, the Agency acknowledges the potential risk of unintended consequences and the need to monitor the data closely. Given that multiple imaging composite APCs were implemented for the first time in CY 2009, data for these APCs will not be available until CY 2010. As a result, CMS decided to not implement any new composite APC policies for at least one year.

NEW TECHNOLOGY APCs (pages 35,304 – 305)

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 one procedure from a New Technology APC to a Clinical APC that contains services exhibiting clinical and resource homogeneity. Thus, HCPCS code 0182T (Hdr elect brachytherapy) would move from New Technology APC 1519 to APC 0313 (Brachytherapy). The reason for the reassignment to a clinical APC is that CMS believes it has gathered sufficient data to determine the appropriate reassignment.

Analysis

The movement from a New Technology APC to a Clinical APC would result in a payment reduction for the procedure from \$1,750 to \$746.68. This represents a 57 percent decrease in payment for this code. We are concerned about such an abrupt reduction. Please let us know if you perform a significant number of these services.

ADJUSTMENT TO APC PAYMENT FOR REPLACED DEVICES THAT RECEIVE PARTIAL OR FULL CREDIT (pages 35,306 – 308)

Background

Certain procedures require that a device be implanted or used to perform the procedure.

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 use these devices and authorizes hospitals to charge less than \$1.01 for these items. The Agency reduces the APC payment for the implantation procedure by 100 percent of the device offset for no cost/full credit cases when both a specified device code is present on the claim and the procedure code maps to a specified APC.⁵

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 required hospitals to report the “FC” modifier for those cases in which a hospital receives a partial credit toward the replacement of a defective device. Payment

⁵ 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.

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.

CMS is using claims that contain the correct device code for the procedure, do not contain token charges, and do not contain the FB modifier signifying that the device was furnished without cost or with a full credit to set payment rates for device-dependent APCs.

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 involve 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 procedure (at least temporarily); and
- c) the device offset amount for the APC must be significant, i.e. it exceeds 40 percent of the cost of the APC.

Proposed Rule

For CY 2010, the Agency is proposing to exclude claims with the FC modifier signifying that the device was furnished with partial credit in order to set payment rates for device-dependent APCs.

Table 19 (at page 35,307) lists the APCs to which the reduction policy for full credit/no cost and partial credit devices would apply in CY 2010 and displays the proposed payment reduction percentages. Table 20 (at page 35,308) lists the devices to which this policy would apply.

In order to determine whether the APCs that were subject to the reduction policy in CY 2009 continue to meet the criteria for reduction in CY 2010, and to determine whether other APCs that were not subject to the reduction policy in CY 2009 would meet the criteria for reduction in CY 2010, CMS examined the offset amounts calculated from the CY 2008 claims data available for this proposed rule. Thus, the Agency proposes to remove twenty APCs and their associated devices.

INPATIENT-ONLY PROCEDURES (pages 35,357 – 358)

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 safely be performed on an outpatient basis.

Proposed Rule

Under the proposed rule, three procedures would be taken off the “inpatient-only” list and paid under the OPSS in CY 2010. The list of procedures proposed to be taken off the “inpatient-only” list is published in Table 37 (page 35,358). This table also contains the proposed APC to which each service would be assigned for payment purposes.

CMS also presented utilization data for CPT code 64818 (Sympathectomy, lumbar) to the APC Panel at the Panel’s request. The APC Panel subsequently recommended that this procedure be performed only in the hospital inpatient setting, and CMS proposes to accept this recommendation and not remove it from the inpatient-only list for CY 2010.

Analysis

AAMC teaching hospitals should review the list in Table 37, 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 35,687 – 35,708) to determine whether any of these can safely be performed in an outpatient setting and, therefore, should be payable under the OPSS.

NEW COVERAGE PROVISIONS FOR KIDNEY DISEASE EDUCATION AND PULMONARY AND CARDIAC REHABILITATION (pages 35,358 – 362)

Background

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) authorized Part B coverage of kidney disease education (KDE) services provided in rural areas and of pulmonary and cardiac rehabilitation services provided to beneficiaries with chronic obstructive pulmonary disease and certain other conditions, effective January 1, 2010.

Proposed Rule

CMS proposes to implement these new MIPPA coverage provisions. More specifically, CMS proposes to pay hospitals for covered KDE services under the Medicare Physician Fee Schedule (MPFS). For pulmonary and cardiac rehabilitation services, CMS proposes to create new HCPCS codes and to establish frequency and duration requirements for the covered therapy.

CMS also notes that in the MPFS, the Agency is proposing to require that pulmonary and cardiac rehabilitation services be supervised by a doctor of medicine or osteopathy. This MPFS requirement would be an exception to the Agency’s proposal in the OPSS proposed rule (discussed above) to permit nonphysician practitioners to directly supervise all hospital outpatient therapeutic services that they may perform themselves.

Analysis

AAMC teaching hospitals that offer these services should review the MPFS proposed requirements for coverage of KDE services and should refer to pages 35,360-61 of the OPFS Proposed Rule for specific details regarding coverage of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

CHANGES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM (pages 35, 375 – 394)

The proposed rule contains changes for the ASC payment system that would be implemented in CY 2010. CMS is proposing to:

- Provide an inflation update of 0.6 percent to ASC payment rates (note that CY 2010 is the first year CMS is permitted by statute to provide an inflation update under the revised ASC payment system);
- Add twenty-eight procedures that are not currently part of the ASC list. These include two procedures for which the American Medical Association's CPT (Current Procedural Terminology) Editorial Panel has created new codes and descriptors, and twenty-six procedures that were previously excluded from payment under the ASC payment system;
- Add six 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 OPFS update; and
- Delete the regulatory requirement that CMS find "good cause" for a hospital-operated ASC that terminated its agreement as an ASC to become a provider-based department of the hospital.

Additionally, based on a MedPAC recommendation that ASCs should be required to submit cost and quality data to allow for the effective evaluation of the adequacy of ASC payment rates, CMS is soliciting comments on the feasibility of ASCs' submitting cost information to the Agency. Specifically, CMS is requesting feedback regarding whether costs should be collected from a sample or the universe of ASCs, the administrative burden associated with collection of cost data, the form that submission of data could take, the expected accuracy of such cost information, and any other issues or concerns. Regarding the collection of quality data, CMS indicates that the agency intends to implement ASC quality reporting in the future, but does not solicit public comment on ASC quality reporting in this OPFS proposed rule.

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 Jennifer Faerberg at jfaerberg@aamc.org or 202-862-6221 for quality-related questions; Lori Mihalich-Levin at lmlevin@aamc.org or (202) 828-0599 for questions related to evaluation and management codes, inpatient-only procedures, new coverage provisions or changes to the ASC payment system; Ivy Baer at ibaer@aamc.org or 202-828-0499 or Diana Mayes, at dmayes@aamc.org, 202-828-0498 for comments related to the physician supervision requirements; and Diana Mayes for other sections of proposed rule.