



**WISCONSIN HOSPITAL
ASSOCIATION**

**SUMMARY OF THE PROPOSED
CALENDAR YEAR 2008
MEDICARE HOSPITAL
OUTPATIENT RULE**

August 2007

SUBMISSION OF COMMENTS

This document provides an overview of the Medicare proposed rule for the Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2008. The Centers for Medicare and Medicaid Services (CMS) must receive comments on the proposal by 5 p.m. on September 14.

CMS requests that comments reference the file code CMS-1392-P and the specific “issue identifier” that precedes the section on which you choose to comment.

Comments can be submitted electronically at: <http://www.cms.hhs.gov/eRulemaking> (Attachments should be in Microsoft Word, WordPerfect, or Excel.)

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I. Overview

CMS published the proposed Medicare Outpatient Prospective Payment System (OPPS) rule for calendar year (CY) 2008 in the August 2, 2007 *Federal Register*. Changes are effective January 1, 2008 unless otherwise noted. This document provides an overview of the proposed rule, additional information regarding the OPPS proposed rule is available on the CMS Web site at: <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

Each section of this summary indicates its location in the *Federal Register* and provides the “issue identifier” CMS requests that you reference in your comments.

Note: Text in italics is extracted from the *Federal Register*.

II. Encounter-Based and Episode-Based Payments under the OPPS

There are multiple issue identifiers for this section. Consult the *Federal Register* for the appropriate issue identifier if you submit a comment on this topic.
Federal Register pages 42648 – 42690

Background: The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient.

According to CMS, success of the OPPS is based on proper packaging and bundling. Packaging refers to when payment for minor, ancillary services associated with a significant procedure are packaged into a single payment for the procedure. Bundling refers to when payment for multiple significant procedures related to an outpatient encounter or to an episode of care should be bundled into a single unit of payment. Packaging and bundling of payments for multiple interrelated services into a single payment creates incentives for providers to furnish services as efficiently as possible.

In the proposed rule, CMS states that the current APC groups reflect a modest degree of packaging, including packaged payment for minor ancillary services, inexpensive drugs, medical supplies, implantable devices, capital-related costs, operating and recovery room use, and anesthesia services. Bundling payment is currently not a common OPPS payment practice because the APC groups generally reflect only the modest packaging associated with individual procedures or services.

As the OPPS has evolved, greater unpackaging of payment has occurred simultaneously with continued growth in OPPS expenditures as a result of increasing volumes of individual services. This unpackaging has occurred because payment under the OPPS has been concentrated on service-specific payment for services furnished to particular patients, rather than on creating incentives for the efficient delivery of services through encounter or episode-of-care-based payment.

CMS believes that the extent of packaging in the OPPS is currently providing an incentive for hospitals to increase the number of individual separately payable services thereby increasing total payments. Furthermore, CMS believes that this aspect of the current OPPS structure is a significant factor in the growth in the program’s volume and spending.

To address this, for this proposed rule, CMS considered two options in an attempt to address growth in OPPS volume and spending. The first alternative would seek to control these increases by adjusting the update to the conversion factor when growth in volume exceeds established tolerances. The second alternative

considered would seek to expand the packaging of supportive ancillary services and ultimately bundle payment for multiple independent services into a single OPSS payment.

For this proposed rule, CMS believes the second alternative (expanded packaging) would create incentives for hospitals to monitor and adjust the volume and efficiency of services delivered. Therefore, as described below, CMS seeks to contain growth in volume and spending by moving away from “service-specific” based payment through expanding the packaging of individual services into APC groups; and the creation of “encounter-based” APCs that would pay a single rate when a certain combination of HCPCS codes are reported on the same date of service rather than paying for individual services under service-specific APCs.

CMS Proposal – Expanded Packaging of Services: “. . . as our initial substantial step toward creating larger payment groups for hospital outpatient care, we are proposing to package payment for items and services in the seven categories listed below into the payment for the primary diagnostic or therapeutic modality to which we believe these items and services are typically ancillary and supportive.”

“We specifically chose these categories of HCPCS codes for packaging because we believe that the items and services described by the codes in these categories are the HCPCS codes that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support.”

“Specifically, we are proposing to package the payment for HCPCS codes describing the dependent items and services in the following seven categories into the payment for the independent services with which they are furnished:

- *Guidance services*
- *Image processing services*
- *Intraoperative services*
- *Imaging supervision and interpretation services*
- *Diagnostic radiopharmaceuticals*
- *Contrast media and*
- *Observation services.”*

Under the expanded packaging proposal, the procedures, identified by HCPCS codes, would change from separately paid to packaged. In these cases, CMS would assign one of two status indicators to these HCPCS codes.

CMS would assign a status indicator of “N” for procedures that would change from separately paid to “unconditionally” packaged. In this case, CMS would always package the cost of the procedure into the costs of the separately paid primary services with which they are billed.

CMS would assign a status indicator of “Q” for procedures that would change from separately paid to “conditionally” packaged. In this case, the procedure would be paid separately in the uncommon instances where no other separately paid primary service is furnished during the outpatient encounter. Otherwise, CMS would package the cost of the procedure into the costs of the separately paid primary services with which they are billed.

This proposal would be implemented in a budget neutral manner by redistributing outpatient dollars to all other services. While this will not result in immediate savings for the Medicare program, CMS believes that the elimination of separate payments for these procedures will have a longer term impact by reducing growth in the volume of services.

In addition, as a result of the proposed packaging policy, CMS is proposing to reassign some HCPCS codes to different clinical APCs for CY 2008 to avoid the two times violations and to ensure continued clinical and resource homogeneity of the APCs. Therefore, the APC median costs change, not only as a result of the

increased packaging, but also as a result of the migration of HCPCS codes into and out of APCs through APC reconfiguration. This may also result in increases or decreases in the payments for HCPCS codes that would not be otherwise affected except for the CY 2008 proposed packaging.

The services impacted by the expanded packaging proposal are available by category on the *Federal Register* page in the heading above.

CMS Proposal – Composite APCs: *“Consistent with our statutory flexibility to define what constitutes a service under the OPSS, we are proposing to view a service, in some cases, as not just the diagnostic or treatment modality identified by one individual HCPCS code but as the totality of care provided in a hospital outpatient encounter that would be reported with two or more HCPCS codes for component services.”*

“Our examination of data for multiple procedure claims identified two specific sets of services that we believe are good candidates for payment based on the naturally occurring common combinations of component codes that we see on the multiple procedure claims. These are low dose rate (LDR) prostate brachytherapy and cardiac electrophysiologic evaluation and ablation services.”

Therefore, for the two specific sets of services identified (low dose rate (LDR) prostate brachytherapy and cardiac electrophysiologic evaluation and ablation services), CMS would pay a single rate when a certain combination of HCPCS codes are reported on the same date of service rather than pay for individual services under the service-specific APCs. However, CMS will pay separately for these procedure codes in those cases where only one of the two procedures is provided in a hospital encounter. The two newly proposed Composite APCs are described below.

CMS Proposal – Low Dose Rate (LDR) Prostate Brachytherapy: *“. . . we are proposing to establish a composite APC, shown in Addendum A as APC 8001, to provide payment for LDR prostate brachytherapy when the composite service, billed as CPT codes 55875 and 77778, is furnished in a single hospital encounter and to base the payment for the composite APC on the median cost derived from claims that contain both codes. These two CPT codes are assigned to status indicator “Q” . . .”*

“. . .we are proposing to continue to pay sources of brachytherapy separately in accordance with the requirements of the statute.”

CMS Proposal – Cardiac Electrophysiologic Evaluation and Ablation Services: *“. . . we are proposing to establish one composite APC, shown in Addendum A as APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite), for CY 2008 that would pay for a composite service made up of any number of services in groups A and B when at least one code from group A and at least one code from group B appear on the same claim with the same date of service. The five CPT codes involved in this composite APC are assigned to status indicator “Q” . . .”*

“We are proposing to continue to pay separately for other separately paid services that are not reported under the codes in groups A and B (such as chest x-rays and electrocardiograms). Moreover, where a service in group A is furnished on a date of service that is different from the date of service for a code in group B for the same beneficiary, we are proposing that payments would be made under the single procedure APCs and the composite APC would not apply.”

The HCPCS codes impacted by this proposal and their group assignment are identified below:

Group A:

| <u>HCPCS</u> | <u>Description</u> | <u>Proposed CY 2008 APC</u> |
|--------------|------------------------------|-----------------------------|
| 93619 | Electrophysiology evaluation | 0085 |
| 93620 | Electrophysiology evaluation | 0085 |

Group B:

| <u>HCPCS</u> | <u>Description</u> | <u>Proposed CY 2008 APC</u> |
|--------------|------------------------------|-----------------------------|
| 93650 | Ablate heart dysrhythm focus | 0085 |
| 93651 | Ablate heart dysrhythm focus | 0086 |
| 93652 | Ablate heart dysrhythm focus | 0086 |

For both composite APC proposals above, the composite APC would have a status indicator of "T" so that payment for other procedures also assigned to status indicator "T" with lower payment rates would be reduced by 50 % when furnished on the same date of service as the composite service, in order to reflect the efficiency that occurs when multiple procedures are furnished to a Medicare beneficiary in a single operative session.

In addition, mental health services are currently paid for as one unit of APC 0034 in cases in which the total payments for specified mental health services provided on the same date of service would otherwise exceed the payment rate for APC 0033. Therefore, payment for mental health services is already based on a composite APC method. For consistency purposes regarding the composite APCs, CMS is proposing to change the status indicator to "Q" for the HCPCS codes for mental health services that comprise this existing composite APC because payment for these services would be packaged unless the sum of the individual payments assigned to the codes would be less than the payment for APC 0034.

CMS considers the proposed composite APCs to be a prototype for future additional composite APCs. CMS notes that the proposed composite APCs are based on observed combinations of component HCPCS codes reported on the same date of service for a single encounter. In future updates, CMS will be exploring how to set payments based on episodes of care involving services that extend beyond the same date but which are all supportive of a single, related course of treatment.

The services impacted by this proposal are available in Addendum M, *Federal Register* page 43129.

III. Reporting of Hospital Outpatient Quality Data

Refer to "Quality Data" if you submit a comment on this issue.

Federal Register pages 42799 - 42806

Background: Currently, there is no requirement for hospitals paid under the OPSS to report quality data to CMS. Therefore, there is currently no link between quality of care and OPSS payments. In contrast, under the inpatient prospective payment system (IPPS), the annual payment update is linked to the collection of quality measures as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Deficit Reduction Act of 2005 (DRA). Under the IPPS, CMS created the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. Hospitals that do not comply with the program requirements receive a reduction to the IPPS annual payment update.

For CY 2007, CMS proposed, but ultimately rejected tying outpatient payments to the inpatient RHQDAPU program, concluding such a program should be based on measures specifically developed to characterize the quality of hospital outpatient care.

The Medicare Improvements and Extension Act of 2006 (MIEA-TRHCA) requires CMS, by CY 2009, to establish a quality reporting program specific to hospital outpatient care using standardized measures of care to receive the full annual update to the OPSS payment rate.

CMS Proposal: ". . . in order for hospitals to receive the full OPSS payment update for services furnished in CY 2009, we are proposing to require that hospital outpatient settings submit data on the following 10 measures, effective with hospital outpatient services furnished on or after January 1, 2008:

- *ED-AMI-1 - Aspirin at Arrival*
- *ED-AMI-2 - Median Time to Fibrinolysis*
- *ED-AMI-3 - Fibrinolytic Therapy Received Within 30 Minutes of Arrival*
- *ED-AMI-4 - Median Time to Electrocardiogram (ECG)*
- *ED-AMI-5 - Median Time to Transfer for Primary PCI*
- *PQRI #5 Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)*
- *PQRI #20 Perioperative Care: Timing of Antibiotic Prophylaxis*
- *PQRI #21 Perioperative Care: Selection of Prophylactic Antibiotic*
- *PQRI #59: Empiric Antibiotic for Community-Acquired Pneumonia*
- *PQRI #1: Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus”*

Hospitals that do not participate in Hospital Outpatient Quality Data Reporting Program (HOP QDRP), withdraw from the program, or fail to meet its requirements will not receive the full OPSS payment rate update in CY 09. Instead, as required by law, those hospitals would receive a reduction of 2.0 percentage points to the outpatient payment update for the affected payment year.

Participation Procedures and Requirements:

To receive the full marketbasket update for CY 2009, hospitals, among other administrative procedures and collection/submission requirements, must complete the Notice of Participation form by November 15, 2007 and begin reporting the ten outpatient quality measures for services furnished on or after January 1, 2008.

To participate in the HOP QDRP for CY 2009 and subsequent calendar years, hospitals must meet administrative, data collection/submission, and data validation requirements. For the most part, these procedures and requirements mirror those currently in place under the IPSS RHQDAPU program. The proposed requirements for the HOP QDRP include:

- participation deadlines and procedures;
- data collection and submission deadlines and procedures;
- data validation;
- an appeals (“reconsideration”) process; and
- a possible attestation procedure.

Details on the proposed requirements for participation in the HOP QDRP are available on *Federal Register* pages 42803 - 42805. The current IPSS RHQDAPU submission procedures can be found on the QualityNet Exchange Web site at <http://www.qualitynet.org>.

Current Proposed and Future Outpatient Quality Measures:

As required by law, the 10 proposed measures have been developed in collaboration with professionals and providers, as well as with the Hospital Quality Alliance (HQA). According to the proposed rule, CMS expects to submit these measures for endorsement by the National Quality Forum (NQF).

The proposed measures include five emergency department-acute myocardial infarction measures and five measures directly related to conditions treated or interventions provided in the hospital outpatient setting (heart failure, community-acquired pneumonia, and diabetes care).

Nine of the ten measures are process measures, while one measure, the diabetes measure (Hemoglobin A1c > 9.0%), is an intermediate outcome measure. Since this measure has not been risk-adjusted, CMS is seeking comment on this outcome measure in relation to the desire for improved quality of care in conjunction with individual patient challenges that may affect results.

Once the HOP QDRP is established, CMS expects to expand the set of measures on which hospital outpatient settings must report data. In the proposed rule, CMS identifies and is seeking comment on an additional 30 measures. Unlike the measures proposed for CY 2008, the 30 additional measures are either

currently in use or were developed for use in settings other than hospital outpatient and have not received formal review by either the HQA or the NQF as measures of outpatient performance.

Although CMS is seeking comment on the 30 additional measures for inclusion in the HOP QDRP for CY 2010 or subsequent calendar years, CMS is also seeking comments on whether any of these additional measures should be included effective for services furnished on or after January 1, 2008 for the CY 2009 update.

The 30 measures under consideration are available on *Federal Register* pages 42801 - 42803.

IV. Ambulatory Payment Classification (APC) Payments

Conversion Factor

Refer to “OPPS: Conversion Factor” if you submit a comment on this issue.

Federal Register page 42693

Background: Outpatient payment rates are determined by multiplying the relative weight for an APC by the conversion factor. The current, 2007 conversion factor is \$61.468.

CMS Proposal: *“The proposed market basket increase update factor of 3.3 percent for CY 2008, the required wage index and rural budget neutrality adjustment of approximately 1.0025, and the proposed adjustment of 0.06 percent for the difference in the pass-through set-aside result in a proposed standard OPSS conversion factor for CY 2008 of \$63.693.”*

Wage Index Adjustment

Refer to “OPPS: Wage Index” if you submit a comment on this issue.

Federal Register pages 42693 - 42695

Background: To account for geographic differences, the labor portion of the conversion factor (60%) is adjusted by the hospital wage index. Currently, CMS applies the wage indexes used for the IPPS to the OPSS conversion factor. These wage indexes also apply to Tax Equity Fiscal Responsibility Act of 1982 (TEFRA) hospitals that participate in OPSS, but not in the IPPS.

CMS Proposal: *“In accordance with our established policy, we are proposing to use the final FY 2008 final version of these wage indices to determine the wage adjustments for the OPSS payment rate and copayment standardized amount that would be published in our final rule with comment period for CY 2008.”*

In adopting the final federal fiscal year (FFY) 2008 IPPS wage indexes, the OPSS will apply all of the adjustments used in the IPPS including:

- a 100% application of the occupational mix adjustment to the average hourly wage used to calculate the wage index using the entire 6-month survey data collected in 2006;
- application of a uniform budget neutrality adjustment to all hospital wage indexes to account for the rural floor adjustment;
- recognition of all reclassifications approved by the Medicare Geographic Classification Review Board (MGCRB);
- continuation of an add-on to the wage index to reflect the commuting patterns of hospital

employees who reside in a county and work in a different area with a higher wage index (the MMA Section 505 “out-migration” adjustment). For CY 2008, CMS will calculate the adjustment using post-reclassified rather than pre-reclassified wage indices;

- expiration of a three-year transition period for urban hospitals that became rural under the new labor area definitions that allowed them to maintain their urban area assignment through December 31, 2007;
- expiration of the special one-time wage index reclassifications granted under Section 508 of the MMA; and
- allocation of a multi-campus hospital’s wages and hours across the different labor market areas where its campuses are located (currently three nationwide) based on Full Time Equivalent (FTE) staff for FFY 2008 and beyond.

Rural Hospital Adjustment

Refer to “OPPS: Rural SCH Payments” if you submit a comment on this issue.

Federal Register page 42698

Background: The MMA required CMS to conduct a study to determine if the cost of providing outpatient care in rural hospitals exceeds the cost in urban hospitals. CMS’ analysis found that all rural hospitals give some indication of having higher cost per unit, but that rural sole community hospitals (SCHs) demonstrated significantly higher cost per unit than urban hospitals. For CYs 2006 and 2007, CMS had provided a 7.1% add-on to the OPPS payment rate for rural SCHs and clarified in 2007 that Essential Access Community Hospitals (EACHs) were also eligible to receive the add-on.

CMS Proposal: *“For CY 2008, we are proposing to continue our current policy of a budget neutral 7.1 percent payment increase for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding drugs, biologicals, and services paid under pass-through payment policy . . .”*

“For CY 2008, we are proposing to include brachytherapy sources in the group of services eligible for the 7.1 percent payment increase because we are proposing to pay them at prospective rates based on their median costs as calculated from historical claims data.”

Transitional Corridor Payments

Refer to “Rural Hospitals Hold Harmless Transitional Payments” if you submit a comment on this issue.

Federal Register pages 42697 - 42698

Background: When the OPPS was implemented, transitional corridor payments were established to provide relief to hospitals that would receive less in payments under the OPPS methodology than they would have received under the prior payment system. Rural hospitals with 100 or fewer beds, cancer hospitals, and children’s hospitals were held harmless and paid the full amount of the difference between the OPPS and the prior payment system. Other hospitals were eligible for partial relief.

For most hospitals, the transitional corridor payments were set to expire on December 31, 2003. The MMA extended transitional corridor payments through December 31, 2005 for rural hospitals with 100 or fewer beds and provided transitional corridor payments during the same period for SCHs located in rural areas. The DRA further extended transitional corridor payments, phasing them out on a percentage basis, through December 31, 2008 for rural hospitals having 100 or fewer beds that are not SCHs (SCHs were provided a 7.1% add-on beginning in CY 2006; see “Rural Hospital Adjustment” section above). Cancer hospitals and children’s hospitals are permanently held harmless from the impact of the OPPS.

CMS Proposal: *“When the OPPS payment is less than the payment the provider would have received under the previous reasonable cost-based system, the amount of payment is increased by . . . 85 percent of the amount of that difference for CY 2008.”*

In addition, CMS clarifies in the proposed rule that EACHs are treated as SCHs and therefore are not eligible for transitional corridor payments.

Cost Outliers

Refer to “OPPS: Outlier Payments” if you submit a comment on this issue.

Federal Register pages 42698 - 42699

Background: Outlier payments are made for individual services or procedures with extraordinarily high costs compared to the payment rates for their APC group. For CY 2007, the outlier threshold is met 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 \$1,825 fixed-dollar threshold. The dual test is intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures. Currently the projected target for aggregate outlier payments is set at 1.0% of aggregate total OPPS payments.

CMS Proposal: *“For CY 2008, we are proposing to continue our policy of setting aside 1.0 percent of aggregate total payments under the OPPS for outlier payments.”*

“In order to ensure that estimated CY 2008 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing that the outlier threshold be set so that outlier payments are 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 \$2,000 fixed-dollar threshold.”

The fixed-dollar threshold increase is due mainly to CMS’ revised methodology used in calculating the overall cost-to-charge ratio (CCR). In addition, the APC recalibration and the proposed changes to packaging caused an increase in the threshold. CMS will continue to pay 50% of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate when the cost of a hospital outpatient service exceeds these thresholds.

Statewide Average Default Cost-to-Charge Ratios

Refer to “OPPS: Statewide Cost-to-Charge Ratios” if you submit a comment on this issue.

Federal Register page 42695

Background: CMS uses CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS. Default CCRs are used for hospitals that are determined to have invalid CCRs, such as new hospitals, hospitals with a CCR that falls outside predetermined floor and ceiling thresholds, or hospitals that have recently given up their all-inclusive rate status.

CMS Proposal: *“. . . we are proposing to update the default ratios for CY 2008 using the most recent cost report data.”*

The proposed New York State default CCRs for both rural and urban for CY 2008 are .4210 and .4177, respectively. *“. . .we are proposing to use the default statewide CCR to determine cost-based payments until the hospital has submitted its first Medicare cost report.”*

Recalibration of APC Weights

Refer to “APC Relative Weights” if you submit a comment on this issue.

Federal Register pages 42635 - 42690

Background: CMS is required to review and revise the APC relative payment weights at least annually. CMS calculated the APC weights for 2007 using claims for services furnished on or after January 1, 2005 and before January 1, 2006.

CMS Proposal: “. . . we are proposing to recalibrate the relative payment weights for each APC based on claims and cost report data for outpatient services.”

“We used outpatient claims for the full CY 2006, processed before January 1, 2007, to set the proposed relative weights for CY 2008.”

“The proposed APC relative weights and payments for CY 2008 . . . continue to be based on the median hospital costs for services in the APC groups.”

A complete discussion of the recalibration of APC weights for CY 2008 can be found on the *Federal Register* pages referenced in the heading above. The proposed APC relative weights and payments, which are based on CY 2006 claims that were processed before January 1, 2007, can be found in Addenda A and B posted on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp>.

Transitional Pass-Through Payments

Pass-Through Spending

Refer to “OPPS: Estimated Transitional Pass-Through Spending” if you submit a comment on this issue. *Federal Register* pages 42743 - 42745

Background: The Balanced Budget Refinement Act of 1999 (BBRA) provides transitional pass-through payments for certain drugs, pharmaceuticals, biologicals, and medical devices. The cap on the total amount of pass-through spending is 2.0% of total OPPS payments. Estimated pass-through spending that does not exceed the 2.0% cap is returned to the conversion factor.

CMS Proposal: “. . . we estimate that total pass-through spending for the 2 device categories and 13 drugs and biologicals that are continuing for pass-through payment into CY 2008 and those that first become eligible for pass-through status subsequent to this proposed rule in CY 2007 or during CY 2008 would equal approximately \$54 million, which represents 0.15 percent of total OPPS projected payments for CY 2008.”

“Because we estimate that pass-through spending in CY 2008 would not amount to 2.0 percent of total projected OPPS CY 2008 spending, we are proposing to return 1.85 percent of the pass-through pool to adjust the conversion factor . . .”

Payment for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Refer to “OPPS: Pass-Through Drugs” if you submit a comment on this issue. *Federal Register* pages 42730 - 42731

Background: The law limits payments for pass-through drugs between two and three years. It has been CMS’ policy to remove drugs from pass-through status as quickly as possible and most are incorporated into the APC rates after two years.

The MMA requires pass-through drugs to be paid at the average sales price (ASP) + 6% for 2005 and thereafter, unless the drug or biological is covered under the Competitive Acquisition Program (CAP). In the latter case, the payment rate is equal to the average price for all competitive acquisition areas and the year established as calculated and adjusted by the Secretary. Therefore, for most cases, the pass-through payment amount for drugs and biologicals is equal to the difference between ASP + 6% and ASP + 5% (the proposed

payment amount for non-pass through drugs and biologicals). The ASP methodology is based on data submitted by manufacturers and is updated quarterly.

CMS Proposal: *“We are proposing to continue pass-through status in CY 2008 for 13 drugs and biologicals. These items, which were approved for pass-through status between April 1, 2006 and July 1, 2007 . . . are assigned status indicator “G” . . .”*

“. . . we are proposing for CY 2008 to pay for pass-through drugs and biologicals that are not part of the Part B drug CAP at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2008.”

“For CY 2008, we are proposing to provide payment for drugs and biologicals with pass-through status that are offered under the Part B drug CAP at a rate equal to the Part B drug CAP rate.”

The proposed rule identifies seven drugs whose pass-through status will expire on December 31, 2007. For CY 2008, no new drugs or radiopharmaceuticals have been granted pass-through status. Furthermore, CMS will continue to use the current methodology to determine payment for pass-through drugs in CY 2008.

Tables identifying the drugs and biologicals, both continuing and expiring, with pass-through status for CY 2008 are available in the *Federal Register* pages referenced in the heading above.

Pass-Through Devices

Refer to “OPPS: Expiring Device Pass-Through Payments” if you submit a comment on this issue.
Federal Register pages 4242727 - 42728

Background: The law limits payments for pass-through devices between two and three years. It has been CMS’ policy to remove devices from pass-through status as quickly as possible and most are incorporated into the APC rates after two years.

Currently, there are three device categories eligible for pass-through payments. For devices, the pass-through payment equals the amount by which the hospital’s charges, adjusted to cost, exceeds the OPSS payment rate associated with the device.

CMS Proposal: *“. . . we are implementing the final decision we discussed in the CY 2007 OPSS/ASC final rule with comment period that finalizes the expiration date for pass-through status for device category C1820{Generator, neurostimulator}. Therefore, as of January 1, 2008, we will discontinue pass-through payment for device category code C1820.”*

“In addition, the 2 device categories . . . C1821{Interspinous process distraction device} . . . and L8690 {Auditory osseointegrated device, includes internal and external components} . . . would be active categories for pass-through payment for 2 years as of December 31, 2008. Therefore, we are proposing that these categories expire from pass-through device payment as of December 31, 2008.”

A table that describes the pass-through device categories noted above, by expiration date, by HCPCS code, is available on *Federal Register* pages referenced in the heading above.

As required by law, CMS deducts from the pass-through payments for the identified devices (two for CY 2008), an amount that reflects the portion of the APC payment amount that CMS determines is associated with the cost of the device. Based on claims data, CMS is unable to identify device costs packaged in the related procedural APCs that are closely identifiable with the two proposed device categories. Therefore, for CY 2008, there is no proposed device offset amount.

VI. Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Reporting of Pharmacy Overhead Charges

Refer to “OPPS: Specified Covered Outpatient Drugs” if you submit a comment on this issue.

Federal Register pages 42733 - 42736

Background: Currently, the payment methodology provides for a single bundled payment representing average hospital acquisition costs and associated pharmacy overhead costs. However, according to a survey done by MedPAC, on hospital charging practices, hospitals set charges for drugs, biologicals, and radiopharmaceuticals high enough to reflect their pharmacy handling costs as well as their acquisition costs. Therefore, CMS is proposing to require that hospitals report pharmacy overhead charges to provide data for possible future payment changes.

CMS Proposal: “. . . we are proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an uncoded revenue code line on the claim beginning in CY 2008.”

“We are proposing to apply this policy to the reporting of charges for all drugs and biologicals, including contrast agents, irrespective of the item's packaged or separately payable status for the CY 2008 OPDS.”

“We are not proposing to apply this policy to the reporting of overhead charges for radiopharmaceuticals given the explicit instructions we gave hospitals beginning in CY 2006 to include the charges for radiopharmaceutical overhead and handling in the charges for the radiopharmaceutical product.”

“Packaging pharmacy overhead for separately payable drugs and biologicals into the payments for drug administration would enhance the accuracy of payments by packaging overhead for similar drugs into the commonly associated separately payable services. . .”

Therefore, once CY 2008 claims data becomes available for rate-setting, this proposal would lead to pharmacy overhead for separately payable drugs being packaged with payment for the associated procedure, likely a drug administration procedure, rather than the current policy where pharmacy overhead for separately payable drugs is packaged with the payment for the drug. However, since claims data reflecting these changes will not be available until CY 2010, CMS is proposing to continue to provide a combined payment rate for acquisition costs and pharmacy overhead for separately payable drugs and biologicals in CY 2008 similar to the combined payment rate provided in CYs 2006 and 2007 that represents the average hospital acquisition cost and pharmacy overhead cost.

Payment and Reporting of Overhead for Specified Covered Outpatient Drugs

Refer to “OPPS: Specified Covered Outpatient Drugs” if you submit a comment on this issue.

Federal Register pages 42733 - 42736

Background: The MMA established a class of drugs called “specified covered outpatient drugs.” These are defined, with certain exceptions, as any existing covered outpatient drug, biological, or radiopharmaceutical agent for which a separate APC exists and for which, in the case of drugs and biologicals, payment was made on a pass-through basis on or before December 31, 2002. Pass-through status for these drugs had expired and they were paid as non-pass-through APC rates. For CYs 2004 and 2005, the MMA required that payment for these drugs be based on a reference average wholesale price (AWP), increasing rates for these drugs.

For CY 2006 and beyond, the MMA requires that payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug for that year as determined by the Secretary of Health and Human

Services (HHS), subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the General Accounting Office (GAO) in 2004 and 2005. For CYs 2006 and 2007, CMS paid for the acquisition and overhead costs of separately paid drugs and biologicals at a combined rate of ASP + 6%.

CMS Proposal - Payment: *“For CY 2008, we are proposing to continue our methodology of providing a combined payment rate for drug and biological acquisition costs and pharmacy overhead.”*

“The results of our data analysis indicate that using mean unit cost to set the payment rates for the drugs and biologicals that would be separately payable in CY 2008 would be equivalent to basing their payment rates, on average, at ASP+5 percent. Therefore, we are proposing to continue to provide a bundled payment for CY 2008 at ASP+5 percent . . .”

Therefore, CMS is proposing to pay for specified covered outpatient drugs using the same payment rate for all other separately payable drugs and biologicals, ASP + 5%.

Payment for Drugs, Biologicals, and Radiopharmaceuticals—Packaging Criteria

Refer to “OPPS: Packaging Drugs and Biologicals” if you submit a comment on this issue.

Federal Register pages 42732 - 42733

Background: The costs of drugs, biologicals, and radiopharmaceuticals are generally packaged into the APC rate for their related procedures or services, unless they are determined to be relatively expensive or are rarely used. Items such as single indication orphan drugs, certain vaccines, and blood and blood products are excluded from the packaging policy. Oral and injectable forms of 5HT3 anti-emetic products are also exempted.

Packaging status is based on a comparison of CMS-calculated per-day cost of the item to a packaging threshold. The packaging threshold for establishing separate APCs for drugs and biologicals was set to \$50 per administration during CYs 2005 and 2006. For CY 2007, CMS finalized a policy to adjust the packaging threshold for inflation using the Producer Price Index (PPI), resulting in a packaging threshold of \$55.

CMS Proposal: *“Following the CY 2007 methodology . . . we used updated fourth quarter moving average PPI levels to trend the \$50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2008 and again rounded the resulting dollar amount (\$57.78) to the nearest \$5 increment, which yielded a figure of \$60.”*

“. . . we are proposing a packaging threshold for CY 2008 of \$60.” For CY 2008, CMS will pay for drugs over the \$60 threshold at ASP + 5%.

Even though CMS is proposing changes in this proposed rule, CMS has expanded their general packaging approach (see the “Encounter-Based and Episode-Based Payments Under the OPSS” section above) in a desire to move the OPSS toward more encounter-based and episode-based payments in the future. CMS states in the proposed rule that they will consider expanded packaging of payment for drugs, biologicals, and radiopharmaceuticals for a future OPSS update.

Payment for Radiopharmaceuticals

There are multiple issue identifiers for this section. Consult the *Federal Register* for the appropriate issue identifier if you submit a comment on this topic.

Federal Register pages 42737 - 42741

Background: Per the MMA, radiopharmaceuticals are exempt from ASP pricing. Because radiopharmaceuticals are considered specified covered outpatient drugs, payments must be made at average

acquisition cost as determined by the Secretary and subject to any adjustment for overhead costs. However, CMS does not have ASP data for radiopharmaceuticals. Therefore, for CYs 2006 and 2007, CMS paid for radiopharmaceuticals at charges reduced to cost using the overall hospital CCR. In CY 2007, CMS stated their intention to develop a suitable prospective payment methodology for radiopharmaceutical products paid under the OPSS in future years, beginning in CY 2008.

In the CY 2008 OPSS proposed rule, CMS has expanded their general packaging approach (see the “Encounter-Based and Episode-Based Payments Under the OPSS” section above) in a desire to move the OPSS toward more encounter-based and episode-based payments in the future. Based on this approach, and CMS’ belief that therapeutic radiopharmaceuticals are distinct from diagnostic radiopharmaceuticals because the primary purpose of providing a therapeutic radiopharmaceutical is the radiopharmaceutical treatment itself, CMS is proposing to differentiate between radiopharmaceutical products, and is making separate payment proposals for “diagnostic” radiopharmaceuticals and “therapeutic” radiopharmaceuticals.

CMS Proposal – Diagnostic Radiopharmaceuticals: “. . . we are proposing to package payment for all diagnostic radiopharmaceuticals and contrast agents that would not otherwise be packaged according to the proposed CY 2008 packaging threshold for drugs, biologicals and radiopharmaceuticals.”

CMS Proposal – Therapeutic Radiopharmaceuticals: “For CY 2008, we are proposing to continue separate payment for therapeutic radiopharmaceuticals that have a mean per day cost of more than \$60, consistent with the packaging methodology applied to other nonpass-through drugs and biologicals.”

“. . . we . . . are proposing . . . to establish prospective payment rates for separately payable therapeutic radiopharmaceuticals using mean costs derived from the CY 2006 claims data, where the costs are determined using our standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges, defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.”

The eight therapeutic radiopharmaceuticals proposed for separate payment for CY 2008 are listed by HCPCS code on Table 44, *Federal Register* page 42740.

Payment for Blood Clotting Factors

Refer to “OPSS: Blood Clotting Factors” if you submit a comment on this issue.
Federal Register page 42736

Background: For CY 2007, CMS provides payment for blood clotting factors at ASP + 6% plus an additional payment for the furnishing fee. The furnishing fee is currently \$0.152 per unit. The furnishing fee provided under the OPSS is updated each year in the Medicare Physician Fee Schedule (MPFS) final rule.

CMS Proposal: “. . . we are proposing to pay for blood clotting factors at ASP+5 percent and to continue our policy for payment of the furnishing fee using the updated amount for CY 2008 as presented in the CY 2008 MPFS final rule.”

In addition, since the furnishing fee update process is statutorily determined and is based on an index (the Consumer Price Index) that is not affected by administrative discretion or public comment, for CY 2009 and thereafter, CMS is proposing to announce the blood clotting furnishing fee by issuing program instructions, hence, eliminating the discussion of the furnishing fee from annual rulemaking.

Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but Without OPPS Hospital Claims Data

Refer to “OPPS: Non-Pass-Through Coded Drugs, Biologicals, and Radiopharmaceuticals without Claims Data” if you submit a comment on this issue.

Federal Register pages 42741 - 42743

Background: For CYs 2005, 2006, and 2007, CMS paid separately for new drugs, biologicals, and radiopharmaceuticals with Healthcare Common Procedure Coding System (HCPCS) codes, but which did not have pass-through status at a rate that was equivalent to the payment they received in the physician office setting (ASP + 6%).

It should be noted that for CY 2008, CMS is proposing a payment rate of ASP + 5% for both pass-through drugs and biologicals and separately payable nonpass-through drugs and biologicals.

CMS Proposal – New Drugs and Biologicals: “. . . for CY 2008, we are proposing to provide payment for these new drugs and biologicals with HCPCS codes as of January 1, 2008, but which do not have pass-through status and are without OPPS hospital claims data, at ASP+5 percent, consistent with our proposed payment methodology for other nonpass-through drugs and biologicals.”

CMS Proposal – New Therapeutic Radiopharmaceuticals: “We are . . . proposing to base payment for new therapeutic radiopharmaceuticals with HCPCS codes as of January 1, 2008, but which do not have pass-through status, on the WACs for these products as ASP data for radiopharmaceuticals are not available.”

CMS Proposal – Non-Pass-Through Drugs and Biologicals Payable in CY 2006 and/or CY 2007 Without CY 2006 Claims Data: “We are proposing to package items for which we estimate the per administration cost to be less than or equal to \$60, which is the general packaging threshold that we are proposing for drugs, biologicals, and radiopharmaceuticals in CY 2008.”

“We are proposing to pay separately for items with an estimated per administration cost greater than \$60. . . . We are proposing that the CY 2008 payment for separately payable items without CY 2006 claims data would be based on ASP+5 percent, similar to other separately payable nonpass-through drugs and biologicals under the OPPS.”

In order to determine the packaging status for these items in CY 2008, CMS calculates an estimate of the per day cost by estimating the average number of units of each product that would typically be furnished to a patient during one administration in the hospital outpatient setting.

In each proposed case above (excluding radiopharmaceuticals for which no ASP are available and payment is based on the WAC), in accordance with the ASP methodology, CMS, in the absence of ASP data, will use the WAC for the product to establish the initial payment rate. If the WAC were also unavailable, CMS would make payment at 95 percent of the most recent AWP available.

Reporting of HCPCS Codes for Part B Drugs

Refer to “OPPS: Non-Pass-Through Coded Drugs, Biologicals, and Radiopharmaceuticals without Claims Data” if you submit a comment on this issue.

Federal Register pages 42742 - 42743

Background: Currently, the OPPS recognizes the lowest available administrative dose of a drug if multiple HCPCS codes exist for the drug. The codes with higher doses are assigned a status indicator "B" indicating that another code exists. Hospitals would then need to bill the code with the lowest available dose and the appropriate number of units in order to receive payment under the OPPS.

CMS Proposal: “We are proposing to allow hospitals to submit claims by reporting any HCPCS code for a Part B drug that is covered under the OPPS, regardless of the unit determination in the HCPCS code descriptor, beginning in CY 2008.”

Because these HCPCS codes were previously unrecognized under the OPPS, CMS does not have claims data to determine the appropriate packaging status. Therefore, CMS will assign these HCPCS codes the same status indicator as the associated recognized HCPCS code (that is, the lowest dose). Once claims data are available for these previously unrecognized HCPCS codes, CMS will determine the packaging status and resulting status indicator for each HCPCS code.

VII. APC Group Changes

There are multiple issue identifiers for this section. Consult the *Federal Register* for the appropriate issue identifier if you submit a comment on this topic.

Federal Register pages 42701 – 42719

As required by law, the proposed rule revises the APC groups to take into account drugs and devices that no longer qualify for pass-through status, new and deleted HCPCS/CPT codes, changes in technologies, new services, and new cost data. In addition, the proposed rule includes input from the Advisory Panel on APC Groups (APC Panel)—an outside panel of experts established by the Balanced Budget Act (BBA) of 1997.

A complete discussion of APC group changes for can be found on the Federal Register pages referenced in the heading above. CMS in the proposed rule for CY 2008 makes significant changes to several status codes which are reflected below. This summary shows the APCs per category for services other than pass-throughs.

| APC Category | Status Indicator | Status | | |
|---|---------------------|------------|------------|------------|
| | | 2006 | 2007 | 2008 |
| Clinic or Emergency Department Visit | V | 6 | 10 | 10 |
| Significant Procedures, Multiple Reduction Applies | T | 208 | 213 | 190 |
| Significant Procedures, No Multiple Reduction | S | 128 | 144 | 127 |
| Ancillary Services | X | 46 | 45 | 38 |
| Pass-Through Devices Categories | H | 55 | 43 | 2 |
| Non-Pass-Through Drugs/Biologicals, Brachytherapy Sources, and Blood and Blood Products | K | 292 | 306 | 305 |
| Partial Hospitalization | P | 1 | 1 | 2 |
| Observation | Q | 1 | 1 | 0 |
| New Technology | S/T | 82 | 81 | 82 |
| Total | | 819 | 844 | 756 |

New Technology APCs

Refer to “New Technology APCs” if you submit a comment on this issue.

Federal Register pages 42703 - 42706

Background: Since CY 2002, CMS retains services within New Technology APC groups until sufficient claims data are available to assign the service to a clinically appropriate APC. This policy allows CMS to move a service from a New Technology APC in less than two years if sufficient data are available or retain a service in a New Technology APC for more than three years if sufficient data are not available. Currently,

new technologies are assigned to cost bands that range from:

- \$0 to \$50 in increments of \$10;
- \$50 to \$100 in an increment of \$50;
- \$100 through \$2,000 in intervals of \$100; and
- \$2,000 through \$10,000 in intervals of \$500.

These intervals are in two parallel sets of new technology APCs, one with status indicator “S” and the other with status indicator “T,” allowing CMS to price New Technology services more appropriately and consistently.

CMS Proposal: “. . . *there are five procedures currently assigned to New Technology APCs for CY 2007 for which we believe . . . have data that are adequate to support their reassignment to clinical APCs. For CY 2008, we are proposing to reassign these procedures to clinically appropriate APCs, applying their CY 2006 claims data to develop their clinical APC median costs upon which payments would be based.*”

In addition, CMS is also proposing to assign Positron Emission Tomography (PET)/Computed Tomography (CT) Scans and IVIG Pre-Administration-Related Services, currently assigned to New Technology APCs, to clinically appropriate APCs, due to the availability of sufficient data. As a result, CMS is proposing to assign seven procedures from New Technology APCs to clinically appropriate APCs for CY 2008.

A complete discussion of new technology APCs including the proposed APC reassignments for CY 2008 can be found on the *Federal Register* pages referenced in the heading above.

Device-Dependent APCs

Refer to “OPPS: Device-Dependent APCs” if you submit a comment on this issue.

Federal Register pages 42719 - 42723

Background: CMS defines device-dependent APCs as procedures that usually cannot be provided without one or more devices. These procedures include insertion of a pacemaker, diagnostic cardiac catheterization, and brachytherapy. Many of the devices involved were once paid as pass-throughs, but are now packaged with the procedure APC. CMS has consistently experienced problems determining payment rates for procedures that include devices and a complete description of the payment history for device-dependent APCs is available on the *Federal Register* pages referenced in the heading above.

For CY 2007, CMS set the median costs for device-dependent APCs using only claims that passed the device edits and included a distinct charge for the devices. Therefore, the median costs for device-dependent APCs for CY 2007 were determined from claims data that theoretically represented the full cost of the device and the procedure.

CMS Proposal: “. . . *the median costs calculated based upon single procedure bills that met all three criteria, that is, correct devices, no token charges, and no "FB" modifier, were generally higher than the median costs calculated using all single bills. We believe that the claims that meet these three criteria . . . reflect the best estimated costs for these device-dependent APCs when the hospital pays the full cost of the device, and we are proposing to base our CY 2008 median costs on the medians calculated based upon these claims.*”

More specifically, CMS will use the same approach used in CY 2007 to calculate median costs for device-dependent APCs, expanding the method to include the exclusion of bills with the modifier “FB” (this modifier identifies a procedure that was performed using an item that was provided without cost to the provider, or where credit was received for a replaced device). Median costs for CY 2008 were calculated using 2006 claims data.

Additionally, in the CY 2008 OPPS proposed rule, CMS has expanded their general packaging approach (see the “Encounter-Based and Episode-Based Payments Under the OPPS” section above) in a desire to move the OPPS toward more encounter-based and episode-based payments in the future. This expanded packaging approach, results in the migration of HCPCS codes and ultimately the proposed deletion and reconfiguration of a number of device-dependent APCs.

A complete description of the device-dependent APCs impacted by the expanded packaging approach is available on the *Federal Register* pages referenced in the heading above.

VIII. Other

Observation Services Payment

Refer to “OPPS: Observation Services” if you submit a comment on this issue.

Federal Register pages 42768 - 42770

Background: Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment, before a decision can be made regarding whether a patient will require further inpatient treatment or if he/she should be discharged from the hospital.

Payment for all observation care under the OPPS was packaged prior to CY 2002. Since CY 2002, separate payment for a single unit of an observation APC for an episode of observation care has been provided in limited circumstances.

In the CY 2008 OPPS proposed rule, CMS has expanded their general packaging approach (see the “Encounter-Based and Episode-Based Payments Under the OPPS” section above) in a desire to move the OPPS toward more encounter-based and episode-based payments in the future. Based on this approach, CMS has proposed to package payment for observation services except in the case of direct admissions for observations.

CMS Proposal: “. . . we are proposing to package payment for observation care reported with HCPCS code G0378 for CY 2008. Payment for observation would be made as part of the payment for the separately payable independent services with which it is billed.”

“. . . we would change the status indicator for HCPCS Code G0378 from "Q" to "N." In addition, we would discontinue recognizing the criteria for separate payment related to hospital visits and "T" status procedures, minimum number of hours, and qualifying diagnoses. However, we would retain as general requirements the criteria related to physician evaluation, documentation, and observation beginning and ending time.”

“We are proposing to continue the coding and payment methodology for direct admission to observation status, as reported using HCPCS code G0379, with the exception of the prior requirement that HCPCS code G0379 is only eligible for separate payment if observation care reported under HCPCS code G0378 does not qualify for separate payment (since this requirement would no longer be applicable).”

Clinic Visits, ED Visits, and Critical Care Services – Payment and Coding

No issue identifier has been provided by CMS for this section.

Federal Register pages 42751 - 42765

Background: Currently, CMS instructs hospitals to use the CY 2007 CPT codes, as well as six HCPCS codes that became effective January 1, 2007, to report clinic visits, emergency department (ED) visits, and

critical care services on claims paid under the OPSS. However, CMS believes that CPT Evaluation and Management (E/M) codes were defined to reflect the activities of physicians and do not describe well the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters.

There are currently three types of visit codes to describe three levels of service; clinic visits, emergency department visits, and critical care visits. However, there is currently no national policy to determine the assignment of E/M codes (CMS is currently developing national guidelines). Hospitals are required to report facility resources for clinic and emergency department visits using CPT E/M codes and to develop internal hospital guidelines to determine what level of visit to report for each patient. While national guidelines are being developed, CMS has advised that each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

CMS Proposal: *“While awaiting the development of a national set of guidelines, we have advised hospitals that each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.”*

The proposed rule contains a lengthy discussion regarding the establishment of a national policy to determine the assignment of E/M codes. The rule addresses guidelines created by the American Hospital Association (AHA) and American Health Information Management Association (AHIMA) and guidelines created by the American College of Emergency Physicians (ACEP). In this discussion, CMS evaluates the guideline models and addresses issues concerning the models, question whether there is a need for national guidelines. CMS is seeking comment on the development of a national policy to determine the assignment of E/M codes. If national guidelines were developed, CMS would provide a minimum of 6-12 months notice to hospitals before implementation to provide sufficient time for providers to make the necessary systems changes and educate their staff.

For clinic visits, CMS will continue to recognize the CPT codes for new and established patients under the OPSS. The HCPCS codes and the corresponding visit APCs are available on *Federal Register* pages referenced in the heading above.

For emergency department (ED) visits, CMS will continue to distinguish between Type A and Type B ED visits (hospitals that maintain an ED and have obligations to the Emergency Medical Treatment and Labor Act (EMTALA) but do not operate a 24-hour ED are referred to as Type B EDs). Type A ED visits would continue to be paid based on the five ED Visit APCs, while Type B ED visits would continue to be paid based on the five Clinic Visit APCs.

Partial Hospitalization

Refer to “OPSS: Partial Hospitalization” if you submit a comment on this issue.

Federal Register pages 42690 - 42693

Background: Partial hospitalization is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care. A partial hospitalization program (PHP) may be provided by a hospital to its outpatients or by a freestanding Community Mental Health Center (CMHC). Under the OPSS providers are paid on a per-diem basis for partial hospitalization services.

Generally, CMS is required to establish relative payment weights based on median costs. Historically, the median per-diem cost for CMHCs has greatly exceeded the median per diem cost for hospital-based PHPs. CMS indicates that hospital-based PHPs are Medicare providers that are required to maintain uniform charges for all payers and therefore, are less likely to significantly change their charges for PHP from year to year, while many CMHCs have indicated that Medicare is their only payer and as a result may have increased and decreased their charges in response to Medicare payment policies including the manipulation

of charges to inappropriately receive outlier payments. As a result, there has been a significant fluctuation in the CMHC median per-diem cost, including significant decreases in both 2005 and 2006, while hospital-based median per-diem costs have remained relatively stable.

To mitigate this drastic reduction in payment, for CYs 2006 and 2007, CMS adopted alternative payment policies for PHP services. For CY 2006, PHP payments were based on a 15% reduction to the combined hospital-based and CMHC median per-diem cost that was used to establish the CY 2005 PHP APC. For 2007, CMS revised its 2006 policy and developed payment for PHP services by applying a 5-percent reduction to the CY 2006 median per diem rate.

CMS Proposal: *“We have developed an alternate way to determine median cost by computing a separate per diem cost for each day rather than for each bill. Under this method, a cost is computed separately for each day of PHP care. When there are multiple days of care entered on a claim, a unique cost is computed for each day of care. All of these costs are then arrayed from lowest to highest and the middle value of the array would be the median per diem cost. Therefore, for CY 2008, we are proposing to adopt this alternate method for computing PHP median per diem costs.”*

This alternative method results in a partial hospitalization APC payment rate of \$179.88 for CY 2008, a 23% percent reduction from the CY 2007 partial hospitalization APC payment rate of \$234.73.

For CY 2008, CMS is proposing to set the outlier threshold for PHP payments to CMHCs at 3.40 times the APC payment amount. Payment to CMHCs for outliers will be made at 50% of the costs in excess of the threshold.

Brachytherapy Payment

Refer to “OPPS: Brachytherapy” if you submit a comment on this issue.
Federal Register pages 42746 - 42750

Background: The MMA required that beginning in CY 2004 all devices of brachytherapy consisting of a seed or seeds (or radioactive source) be paid based on a facility’s charges for the service, adjusted to cost. In addition, because brachytherapy sources are paid at cost, they are excluded from outlier payments and from any budget-neutrality requirements. To accommodate this MMA requirement, CMS revised the status codes for brachytherapy sources to “H” and revised the definition of status code “H” to include non-pass-through brachytherapy sources paid on a cost basis. This provision was set to expire at the end of CY 2006.

For CY 2007, CMS finalized a policy of prospective payment based on median costs for brachytherapy sources. However, MIEA-TRHCA of 2006 extended, for one-year, the MMA provision described above, paying for brachytherapy based on charges adjusted to cost. This provision expires on December 31, 2007.

CMS Proposal: *“We are proposing to pay separately for each of the [brachytherapy] sources . . . on a prospective basis for CY 2008, with payment rates to be determined using the CY 2006 claims-based median cost per source for each brachytherapy device.”*

“. . . we are proposing to assign future new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.”

For CY 2008, brachytherapy source APCs will be assigned status indicator “K” and be subject to budget neutrality. In addition, because brachytherapy sources will now be paid on a prospective basis, these sources will be eligible to receive additional payments under certain circumstances through the outlier provisions and the 7.1% rural SCH adjustment.

Refer to Table 48, *Federal Register* pages 42749 – 42750 for the proposed brachytherapy sources for CY 2008.

Inpatient-Only Procedures Payment

Refer to “OPPS: Inpatient Procedures” if you submit a comment on this issue.

Federal Register pages 42779 - 42771

Background: CMS identifies procedures that are typically provided only in an inpatient setting, and therefore, would not be paid by Medicare under the OPPS. These procedures comprise what is referred to as the “inpatient list.” The inpatient list specifies those services that will only be paid when provided in an inpatient setting because of the nature of the procedure and the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. These procedures are assigned a status code of “C” and hospitals are advised to admit beneficiaries requiring these procedures to receive payment. Each year CMS, with input from the APC Panel, reviews the inpatient only list using specific criteria to determine whether any procedures should be moved from the inpatient list and assigned to an APC.

CMS Proposal: “. . . we are proposing to accept the APC Panel's recommendation to remove the 13 procedures from the OPPS inpatient list for CY 2008 and to assign them to clinically appropriate APCs . . .”

“We also are accepting the recommendation from the APC Panel to gather additional utilization information for CPT codes 20660 and 64818, which we will provide to the APC Panel at its next meeting.”

Table 56, *Federal Register* page 42771, shows the 13 procedures proposed for removal from the inpatient list. The changes to the inpatient list will be effective for services furnished on or after January 1, 2008.

Devices Replaced with No Cost or Hospital Receives Credit

Refer to “OPPS: Device-Dependent APCs” if you submit a comment on this issue.

Federal Register pages 42723 - 42727

Background: In recent years there have been several field actions and recalls with regard to failure of implantable devices. In many of these cases, the manufacturers have offered replacement devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device.

For CY 2007, CMS implemented a policy that reduced the payment for select device-dependent APCs when the hospital receives certain replacement devices without cost or receives a full credit for the device being replaced. This policy does not apply to cases in which there is a partial credit toward the replacement of the device.

CMS Proposal: “. . . we are proposing to create a HCPCS modifier to be reported on a procedure code . . . if a device . . . is replaced with partial credit from the manufacturer that is greater than or equal to 20 percent of the cost of the replacement device and to reduce the payment for the procedure by 50 percent of the amount of the estimated packaged cost of the device being replaced when the modifier is reported with a procedure code that is assigned to an APC. . .”

“We also are proposing to base the beneficiary's copayment on the reduced APC payment rate so that the beneficiary shares in the hospital's reduced costs.”

Table 38 on *Federal Register* page 42776 lists the APCs impacted and the device offset amounts applicable in cases of no cost or full or partial credit for replaced devices for CY 2008.

In addition, CMS is implementing the adjustment through the use of an appropriate modifier (modifier FB). Hospitals must append the modifier to the HCPCS code for the procedure in which the device was inserted on claims when the device that was furnished in cases of no cost or full or partial credit for a replaced device identified in Table 39 on *Federal Register* page 42727.

Critical Access Hospitals (CAHs) – Necessary Provider CAHs

Refer to “Necessary Provider CAHs” if you submit a comment on this issue.

Federal Register pages 42806 - 42807

Background: In order to be designated as a CAH, among other criteria, a CAH must be located in a rural area and must meet a distance requirement (at least 35-miles or, in the case of mountainous terrain or in areas with only secondary roads, 15-miles from the nearest hospital or other CAH). Payment for outpatient services to CAHs is based on 101 percent of reasonable costs.

Prior to January 1, 2006, States were permitted to waive the CAH minimum distance eligibility requirement by certifying that a CAH was a necessary provider. The MMA ended States' authority to waive the location requirement for a CAH by certifying CAHs as a necessary provider, effective January 1, 2006. In the proposed rule, CMS addresses situations that resulted from the “necessary provider” designation.

CMS Proposal – Co-Location of Necessary Provider CAHs: “. . . we are proposing to no longer allow a necessary provider CAH to enter into co-location arrangements between CAHs and hospitals unless such arrangements were in effect on or before January 1, 2008 and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change.”

“. . . we are proposing to clarify that a change of ownership of the CAH, when the new owners assume the original provider agreement, does not constitute a new co-location arrangement and, thereby, under our proposal, a necessary provider CAH would be permitted to continue under an existing co-location arrangement.”

CMS Proposal – Provider-Based Facilities of CAHs: “. . . we are proposing to clarify that if a necessary provider CAH, or a CAH that does not have a necessary provider designation, operates a provider-based facility . . . , or a psychiatric or rehabilitation distinct part unit . . . that was created or acquired on or after January 1, 2008, it must comply with the distance requirement of a 35-mile drive to the nearest hospital or CAH (or 15 miles in the case of mountainous terrain or in areas with only secondary roads).”

CMS Proposal – Termination of Provider Agreement: “In the event that a CAH with a necessary provider designation enters into a co-location arrangement after January 1, 2008, or acquires or creates an off-campus facility after January 1, 2008, that does not satisfy the CAH distance requirements . . . , we are proposing to terminate that CAH's provider agreement . . .”

“The necessary provider CAH could avoid termination by converting to a hospital that is paid under the IPPS, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program . . .”

Hospital Conditions of Participation (CoPs)

Refer to “Hospital CoPs” if you submit a comment on this issue.

Federal Register pages 42807 - 42810

Background: On November 27, 2006, CMS published a final rule in relation to four of the current requirements (conditions of participation (CoPs) that hospitals must meet to participate in the Medicare and Medicaid programs including:

- completion of the history and physical examination in the Medical staff and the Medical record services CoPs;
- authentication of verbal orders in the Nursing services and the Medical record services CoPs;
- securing medications in the Pharmaceutical services CoP; and
- completion of the postanesthesia evaluation in the Anesthesia services CoP.

Since publication of this rule, CMS states that many have sought clarification on the application of these requirements for patients undergoing outpatient surgeries and procedures. In the proposed rule, CMS is proposing revision to the current regulations to address these concerns.

CMS Proposal - Medical History and Physical Examination: *“We are proposing revisions . . . that would require an updated examination, including any changes in a patient's condition, to be completed and documented for each patient after admission or registration and prior to surgery or to a procedure requiring anesthesia services.”*

“However, under these proposed requirements, it is not our intent to include those minor procedures that only require the administration of local anesthetics, as might be the case for procedures such as biopsies of skin lesions or suturing of noncomplex lacerations.”

CMS Proposal – Post-Anesthesia Evaluation: *“. . . we are proposing revisions . . . that would ensure that all patients who have received anesthesia services, regardless of inpatient or outpatient status, have a postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia before they are discharged or transferred from the postanesthesia recovery area.”*