



**WISCONSIN HOSPITAL
ASSOCIATION**

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

November 2007

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I. Overview

The Centers for Medicare and Medicaid Services (CMS) published the final Medicare Outpatient Prospective Payment System (OPPS) rule with comment period for CY 2008 in the November 27, 2007 *Federal Register*. Changes are effective January 1, 2008 unless otherwise noted. This document provides an overview of the final rule. Additional information regarding the OPPS is available on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

Note: Text in italics is extracted from either the August 2, 2007 or the November 27, 2007 *Federal Registers*.

II. Encounter-Based and Episode-Based Payments Under the OPPS (Expanded Packaging and Composite APCs)

Federal Register pages 66610 – 66670

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 payments for multiple significant procedures related to an outpatient encounter or to an episode of care are 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 stated 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 un-packaging of payment has occurred simultaneously with continued growth in OPPS expenditures as a result of increasing volumes of individual services. This un-packaging 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 the proposed rule, CMS considered two options. 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 would seek to expand the packaging of supportive ancillary services and ultimately bundle payment for multiple independent services into a single OPPS payment.

CMS believes the second alternative (expanded packaging) will create incentives for hospitals to monitor and adjust the volume and efficiency of services delivered. Therefore, as described below, CMS proposed to

seek 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.*”

CMS Final Rule—Expanded Packaging of Services: CMS has adopted the above proposal as final.

In adopting this proposal, CMS has responded to comments, modifying and refining its proposal specific to packaging payment under the following categories: diagnostic radiopharmaceuticals; imaging supervision and interpretation services; contrast agents; and creating composite APCs for observation services (see the “CMS Final Rule—Extended Assessment & Management Composite” section below).

Table 10 ([Federal Register pages 66659 – 66664](#)) contains a comprehensive list of all procedures in the final seven categories for which payment will be packaged either conditionally or unconditionally.

Under the expanded packaging policy, 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 will assign a status indicator of “N” for procedures that will change from separately paid to “unconditionally” packaged. Furthermore, CMS will always package the cost of the procedure into the costs of the separately paid primary services with which they are billed.

In addition, CMS will assign a status indicator of “Q” for procedures that will change from separately paid to “conditionally” packaged. In this case, the procedure is either packaged or separately paid, depending on the services with which it is reported. There are two subsets of the “special” packaged codes for the purpose of payment:

- imaging supervision and interpretation “special” packaged codes are named ‘T-packaged’ codes; and
- all other “special” packaged codes are referred to as “STVX-packaged” codes.

Payment for a HCPCS code with a status indicator of “Q” is packaged unless:

- the HCPCS code is not reported on the same day with a service that has a status indicator of “S,” “T,” “V,” or “X,” in which case it would be paid separately. CMS refers to this situation as “STVX-packaged”; or
- the HCPCS code is not reported on the same day with a service that has a status indicator of “T,” in which case it would be paid separately. CMS refers to this situation as “T-packaged”.

Payment for a HCPCS code with a status indicator of “Q” that is assigned to a composite APC will be packaged into the payment for the composite APC when the criteria for payment of the composite APC are met (see composite APC discussion below).

This policy will 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 expanded packaging policy, CMS will 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 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 expanded packaging.

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.”

CMS Final Rule—Composite APCs: CMS has adopted the above proposal as final and has adopted two additional composite APCs in the final rule.

“. . . we believe that it is appropriate to establish under the OPSS a single payment for multiple independent procedures that are frequently furnished together. For that reason, we are adopting five composite APCs for CY 2008 and intend to explore developing others.”

The five composite APCs for CY 2008 are:

Proposed and Adopted as Final:

- APC 8000 – Cardiac Electrophysiologic Evaluation and Ablation Composite
- APC 8001 – Low Dose Rate (LDR) Prostate Brachytherapy Composite

New in the Final Rule and Adopted as Final:

- APC 8002 – Level I Extended Assessment & Management Composite
- APC 8003 – Level II Extended Assessment & Management Composite

Current APC now identified as a Composite APC:

- APC 0034 – Mental Health Services Composite

Addendum M (*Federal Register* pages 67224 – 67225) lists the services, identified by HCPCS code, for assignment to composite APCs for CY 2008. Each composite APC is described in detail below.

CMS Proposal—LDR Prostate Brachytherapy Composite: “. . . 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 Final Rule—LDR Prostate Brachytherapy Composite: CMS has adopted the above proposal as final with no revisions.

CMS Proposal—Cardiac Electrophysiologic Evaluation and Ablation Services Composite: “. . . 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.”

CMS Final Rule—Cardiac Electrophysiologic Evaluation and Ablation Services: CMS has adopted the above proposal as final with no revisions.

The HCPCS codes applicable to the Cardiac Electrophysiologic Evaluation and Ablation Composite APC (APC 8000) and their group assignment are:

Group A:

<u>HCPCS</u>	<u>Description</u>	<u>Final CY 2008 APC</u>
93619	Electrophysiology evaluation	0085
93620	Electrophysiology evaluation	0085

Group B:

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

CMS will pay separately for the procedure codes associated with both of these composite APCs (APCs 8000 and 8001) in cases where only one of the two procedures is provided in a hospital encounter. For both

composite APCs listed 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.

CMS Final Rule—Extended Assessment & Management Composite: For CY 2008, CMS is eliminating separate OPSS payments for observation services (as described in the “CMS Final Rule—Expanded Packaging of Services” above; and “Observation Services Payment”, Section VIII below). For the most part, observation services will be packaged as part of the payment for the separately payable services with which they were billed. However, for CY 2008, CMS is creating two additional composite APCs (not identified in the proposed rule) that will pay hospitals for extended assessment and management, of which observation care is a component major service.

“. . . we are creating two new composite APCs for CY 2008, APCs 8002 (Level I Extended Assessment and Management Composite) and 8003 (Level II Extended Assessment and Management Composite).”

“APC 8002 describes an encounter for care provided to a patient that includes a high level (Level 5) clinic visit or direct admission to observation in conjunction with observation services of substantial duration.”

“APC 8003 describes an encounter for care provided to a patient that includes a high level (Level 4 or 5) emergency department visit or critical care services in conjunction with observation services of substantial duration.”

The following logic will apply to the two Extended Assessment and Management Composite APCs (APCs 8002 and 8003):

APC 8002 will be assigned when:

- 8 or more units of HCPCS code G0378 (Hospital observation service, per hour) are billed –
 - On the same day as HCPCS code G0379 (Direct admission of patient for hospital observation care);
 - OR-
 - On the same day or the day after –
 - CPT code 99205 (Office or other outpatient visit for the evaluation and management of a new patient (Level 5)); or
 - CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient (Level 5)).

APC 8003 will be assigned when:

- 8 or more units of HCPCS code G0378 (Hospital observation service, per hour) are billed on the same day or the day after:
 - CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); or
 - CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)); or
 - CPT code 99291 (Critical care, evaluation and management of the critically ill or

critically injured patient; first 30-74 minutes).

For these composite APCs, if a hospital provides a service with status indicator “T” on the same date of service, or one day earlier than the date of service associated with HCPCS code G0378, the hospital will not be eligible for payment under APC 8002 or 8003.

There is no diagnosis requirement for purposes of these composite APCs; patients with any diagnosis may trigger payment of APC 8002 or 8003. If any of the criteria for these composite APCs (described above) are not met, payment would not be made through APC 8002 or 8003. Instead, payment for any separately payable services, including the clinic visit, ED visit, or critical care visit would be made through the usual associated APCs.

Payment for a direct admission to observation will be made according to the usual HCPCS code G0379 payment criteria (see “Observation Services Payment”, Section VIII below) and payment for HCPCS code G0378 alone will be packaged.

CMS Final Rule—Mental Health Services: As discussed in the proposed rule, 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 changing 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.

III. Reporting of Hospital Outpatient Quality Data

Federal Register pages 66860 – 66877

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.”

CMS Final Rule: For CY 2008, CMS has adopted seven of the ten proposed outpatient quality measures under the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). In order to receive the full

OPPS payment update for services furnished in CY 2009, providers are required to submit data on the seven outpatient measures effective for hospital outpatient services furnished on or after April 1, 2008. Non-compliant providers in CY 2008 will receive the OPPS update reduced by 2.0 percentage points in CY 2009.

The final measures which have been endorsed by the National Quality Forum (NQF) include five emergency department-acute myocardial infarction (ED-AMI) measures and two Perioperative Care measures. All seven of the measures are process measures. The seven outpatient measures adopted by CMS are:

- 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 #20 Perioperative Care: Timing of Antibiotic Prophylaxis
- PQRI #21 Perioperative Care: Selection of Prophylactic Antibiotic

The following outpatient quality measures were proposed but not finalized for CY 2008:

- PQRI #59: Empiric Antibiotic for Community-Acquired Pneumonia
- PQRI #1: Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus
- PQRI #5 Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Hospitals that do not participate in the HOP QDRP, withdraw from the program, or fail to meet its requirements will not receive the full OPPS payment rate update in CY 2009. Instead, as required by law, those hospitals will receive a 2.0 percentage point reduction to the outpatient payment update for the affected payment year. For subsequent years, CMS expects to expand the set of measures on which hospital outpatient settings must report data.

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 January 31, 2008 and begin reporting the seven outpatient quality measures for services furnished on or after April 1, 2008.

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

- participation deadlines and procedures;
- data collection and submission deadlines and procedures; and
- an appeals (“reconsideration”) process.

For CY 2008, CMS did not finalize the proposed attestation procedure or validation of data as requirements for purposes of the CY 2009 payment update. However, CMS states that it is their intent to implement these requirements for CY 2010 and subsequent years.

Details on the final requirements for participation in the HOP QDRP are available on *Federal Register* pages referenced in the heading above. The submission procedures can be found on the QualityNet Exchange Web site at <http://www.qualitynet.org>.

IV. Ambulatory Payment Classification Payments

Conversion Factor

Federal Register pages 66677 – 66678

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 OPPS conversion factor for CY 2008 of \$63.693.”*

CMS Final Rule: *“The market basket increase update factor of 3.3 percent for CY 2008, the required wage index and rural budget neutrality adjustment of approximately 1.0019, and the adjustment of 0.12 percent for the difference in the pass-through set-aside resulted in a final standard OPPS conversion factor for CY 2008 of \$63.694.”*

Wage Index Adjustment

Federal Register pages 66678 – 66680

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 OPPS conversion factor. These wage indexes also apply to Tax Equity Fiscal Responsibility Act of 1982 (TEFRA) hospitals that participate in OPPS, 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 OPPS payment rate and copayment standardized amount that would be published in our final rule with comment period for CY 2008.”*

CMS Final Rule: For CY 2008, CMS will apply all of the adjustments used in the final federal fiscal year (FFY) IPPS wage indexes including:

- a 100% application of the occupational mix adjustment to the average hourly wage used to calculate the wage index using the entire six-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.

For the first time, the final FFY 2008 IPPS wage indexes include a blanket budget neutrality adjustment for including the rural floor provision, which previously had been applied to the IPPS standardized amount. For the OPSS, CMS is increasing the conversion factor by the proportional amount of the rural floor budget neutrality adjustment to accommodate this change.

Rural Hospital Adjustment

Federal Register page 66683

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 OPSS 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 OPSS, 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.”

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

Transitional Corridor Payments

Federal Register pages 66682 – 66683

Background: When the OPSS was implemented, transitional corridor payments were established to provide relief to hospitals that would receive less in payments under the OPSS 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 OPSS 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 OPSS.

CMS Proposal: *“When the OPSS 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.”*

CMS Final Rule: CMS has adopted the above proposal as final with no revisions. In addition, CMS clarified in the final rule that EACHs are treated as SCHs and therefore are not eligible for transitional corridor payments.

Cost Outliers

Federal Register pages 66683 – 66686

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 OPSS 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 OPSS 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 OPSS, 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.”

CMS Final Rule: *“We estimate that a fixed-dollar threshold of \$1,575, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPSS payments to outlier payments.”*

The fixed-dollar threshold has been reduced by \$425 from the proposed rule. According to CMS, this decrease is based on applying final payment policies using more recent claims and cost report data to estimate the threshold that would allow outlier payments to meet the 1.0% target of total CY 2008 OPSS payments.

Beginning in CY 2008, brachytherapy sources will be eligible for outlier payment. In addition, the costs of diagnostic radiopharmaceuticals and contrast media for which CY 2008 payment is packaged into the APC payments for nuclear medicine and other imaging procedures (see “Encounter-Based and Episode-Based Payments Under the OPSS”, Section II) will contribute to a claim’s eligibility for outlier payment in CY 2008.

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

Federal Register pages 66680 – 66682

Background: CMS uses CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPSS. 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.”*

CMS Final Rule: CMS has adopted the above proposal as final. The CY 2008 average default CCRs by state are available on *Federal Register* pages referenced in the heading above.

Recalibration of APC Weights

Federal Register pages 66588 – 66610

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.”

CMS Final Rule: CMS has adopted the above proposal as final, expanding the claims set to claims that were processed before June 30, 2007.

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 final APC relative weights and payments, which are based on CY 2006 claims that were processed before June 30, 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> - TopOfPage.

V. Transitional Pass-Through Payments

Pass-Through Spending

Federal Register pages 66777 – 66779

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 OPSS payments. Estimated pass-through spending that does not exceed the 2.0% cap is returned to the conversion factor.

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

CMS Final Rule: *“Because we estimate that pass-through spending in CY 2008 will not amount to 2.0 percent of total projected OPSS CY 2008 spending, we will return 1.91 percent of the pass-through pool to adjust the conversion factor . . .”*

Payment for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Federal Register pages 66752 – 66756

Background: The law limits payments for pass-through drugs to 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 applicable fee schedule portion associated with the drug or biological). 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.”

CMS Final Rule: CMS has adopted the above proposal as final.

In addition, CMS has granted pass-through status in CY 2008 to an additional six drugs and biologicals. A listing of the drugs and biologicals with pass-through status in CY 2008 is available in Table 28 ([Federal Register page 66756](#)).

A listing of the drugs and biologicals whose pass-through status is expiring in CY 2008 is available in Table 27 ([Federal Register page 66754](#)).

Pass-Through Devices

[Federal Register pages 66749 – 66751](#)

Background: The law limits payments for pass-through devices to 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.

In CY 2007, 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 OPPS payment rate associated with the device.

CMS Proposal: *“. . . we are implementing the final decision we discussed in the CY 2007 OPPS/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{Interspinoous 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.”

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

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

Reporting of Pharmacy Overhead Charges

Federal Register pages 66759 – 66762

Background: Currently, the payment methodology for separately payable drugs provides for a single bundled payment representing average hospital acquisition costs and associated pharmacy overhead costs. According to a survey done by the Medicare Payment Advisory Commission (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.

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. . .”

Once CY 2008 claims data became available for rate-setting, this proposal would have allowed for packaging of pharmacy overhead for separately payable drugs 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. Since the claims data required to implement these changes would not have been available until CY 2010, CMS proposed to continue providing 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.

CMS Final Rule: “. . . we are not finalizing our proposal to require hospitals to remove pharmacy overhead costs from drug acquisition costs and to report pharmacy overhead costs in an uncoded revenue code line.”

“While we continue to believe that packaging pharmacy overhead costs into the associated independent procedures for administration of the drugs could pay hospitals more appropriately for the variable pharmacy overhead costs associated with different types of drugs, we are concerned about the operational challenges and administrative burdens that hospitals would face in reporting drugs provided in the HOPD.”

“. . . we are finalizing our proposal to provide a single bundled payment for separately payable drugs and biologicals, inclusive of both drug acquisition and pharmacy overhead costs. Hospitals should continue to consider the costs of pharmacy overhead in developing and reporting their charges for drugs and biologicals, maintaining their current practice.”

Therefore, for CY 2008, pharmacy overhead and handling costs will be recognized within drug charges and be paid through the packaged or separate drug payment (as appropriate based on the drug packaging threshold).

Payment for Specified Covered Outpatient Drugs

Federal Register pages 66762 – 66765

Background: The MMA established a class of drugs called “specified covered outpatient drugs” (SCODs). 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: *“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 . . .”

CMS Final Rule: *“Our claims data for the CY 2007 and CY 2008 final rules consistently have shown equivalent average ASP-based amounts for separately payable drugs and biologicals that are lower than ASP+6 percent, specifically ASP+4 percent and APC+3 percent, respectively.”*

“However, because we have been paying ASP+6 percent for separately payable drugs and biologicals under the OPSS for the last 2 years, we believe it is appropriate to transition to the use of hospital claims data as the basis for the relative ASP percent. Therefore, we will provide a 2-year transition, with a one year transitional payment rate in CY 2008. . .”

“. . . we will provide a transitional payment of ASP+5 percent for separately payable drugs and biologicals and associated pharmacy overhead in CY 2008 as we move toward a relative ASP percent based on mean costs from claims for CY 2009.”

Therefore, for CY 2008, CMS is will pay for SCODs using the same payment rate for all other separately payable drugs and biologicals, ASP + 5%. However, using the adopted methodology to use hospital claims data as the basis for the relative ASP percent, payment for SCODs for CY 2009 and thereafter, will likely be lower than adopted payment rate of ASP + 5%.

Payment for Drugs, Biologicals, and Radiopharmaceuticals—Packaging Criteria

Federal Register pages 66756 – 66759

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: “. . . we are proposing a packaging threshold for CY 2008 of \$60.”

“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.”

For CY 2008, CMS will pay for drugs over the \$60 threshold at ASP + 5%.

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

Payment for Radiopharmaceuticals

Federal Register pages 66765 – 66772

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 its intention to develop a suitable prospective payment methodology for radiopharmaceutical products paid under the OPSS in future years, beginning in CY 2008.

For this final rule, CMS has expanded its general packaging approach (see “Encounter-Based and Episode-Based Payments Under the OPSS”, Section II) 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, CMS has adopted 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 Final Rule—Diagnostic Radiopharmaceuticals: CMS has adopted the above proposal as final with no revisions.

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.”

CMS Final Rule—Therapeutic Radiopharmaceuticals: CMS has adopted the above proposal as final. The eight separately payable therapeutic radiopharmaceuticals for CY 2008 are listed by HCPCS code in Table 31 (*Federal Register page 66772*).

Payment for Blood Clotting Factors

Federal Register page 66765

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.”

CMS Final Rule: CMS has adopted the above proposal as final with no revisions. For future updates, CMS will announce the updated blood clotting factor furnishing fee using applicable program instructions, posting these instructions on the CMS website.

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

Federal Register pages 66772 – 66777

Background: For CYs 2005, 2006, and 2007, CMS paid separately for new drugs, biologicals, and radiopharmaceuticals with 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%).

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 OPSS hospital claims data, at ASP+5 percent, consistent with our proposed payment methodology for other nonpass-through drugs and biologicals.”

CMS Final Rule—New Drugs and Biologicals: CMS has adopted the above proposal as final with no revisions.

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 Final Rule—New Therapeutic Radiopharmaceuticals: CMS has adopted the above proposal as final with no revisions.

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 OPSS.”

CMS Final Rule—Non Pass-Through Drugs and Biologicals Payable in CY 2006 and/or CY 2007 Without CY 2006 Claims Data: CMS has adopted the above proposal as final with no revisions.

In order to determine the packaging status for these items in CY 2008, CMS calculated an estimate of the per

day cost by multiplying the payment rate based on ASP+5 percent, by an estimated 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 case above, excluding radiopharmaceuticals for which no ASP are available and payment is based on the wholesale acquisition cost (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 is also unavailable, CMS will make payment at 95 percent of the most recent AWP available.

Reporting of HCPCS Codes for Part B Drugs

Federal Register pages 66776 – 66777

Background: Currently, the OPSS 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 OPSS.

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 OPSS, regardless of the unit determination in the HCPCS code descriptor, beginning in CY 2008.”*

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

Hospitals that may be burdened by reporting multiple HCPCS codes need not change their current billing practices, but hospitals that would like additional flexibility when billing for drugs with multiple HCPCS dosages may implement these changes beginning in CY 2008.

Because these HCPCS codes were previously unrecognized under the OPSS, 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

Federal Register pages 66688 – 66739

As required by law, the final 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 final 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 final 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	2006	2007	2008
	Indicator			
Clinic or Emergency Department Visit	V	6	10	12
Significant Procedures, Multiple Reduction Applies	T	208	213	188
Significant Procedures, No Multiple Reduction	S	128	144	128
Ancillary Services	X	46	45	39
Pass-Through Devices Categories	H	55	43	2
Non-Pass-Through Drugs/Biologicals, Brachytherapy Sources, and Blood and Blood Products	K	292	306	324
Partial Hospitalization	P	1	1	2
Observation	Q	1	1	0
New Technology	S/T	82	81	82
Total		819	844	777

For CY 2008, CMS will discontinue the use of status indicator “H” for brachytherapy source APCs and therapeutic radiopharmaceuticals APCs, and designate them as a status indicator “K”.

New Technology APCs

Federal Register pages 66694 – 66699

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 proposed 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 proposed to assign seven procedures from New Technology APCs to clinically appropriate APCs for CY 2008.

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

A complete discussion of new technology APCs including the final APC reassignments for CY 2008 can be

found on the *Federal Register* pages referenced in the heading above.

Device-Dependent APCs

Federal Register pages 66739 – 66743

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. 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.”

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

For CY 2008, 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 a modifier signifying that the device was furnished without cost or with full credit (see “Devices Replaced with No Cost or Hospital Receives Credit”, Section VIII). CY 2008 payment rates for device-dependent APCs are based on their median costs calculated from CY 2006 claims and the most recent cost report data.

Additionally, in this final rule, CMS has expanded their general packaging approach (see “Encounter-Based and Episode-Based Payments Under the OPPS”, Section II) 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

Federal Register pages 66810 – 66815

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.

CMS Proposal—Observation Services (HCPCS code G0378): “. . . 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.”

CMS Final Rule—Observation Services (HCPCS code G0378): “. . . we are adopting our proposal to package payment for observation care reported with HCPCS code G0378 for CY 2008, with a modification to establish two new composite APCs for extended assessment and management.”

See “Encounter-Based and Episode-Based Payments Under the OPPS”, Section II for a complete description of the packaging of observation services and description of the composite APCs developed for extended observation care.

CMS Proposal—Direct Admission to Observation (HCPCS code G0379): “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).”

CMS Final Rule—Direct Admission to Observation (HCPCS code G0379): CMS has adopted the above proposal as final.

“. . . payment for direct admission to observation will be made either under composite APC 8002 (Level I Prolonged Assessment and Management Composite) or under APC 0604. The composite APC will apply, regardless of the patient’s particular clinical condition, if the hours of observation services (HCPCS code G0378) are greater than or equal to eight and billed on the same date as HCPCS code G0378 and there is not a “T” status procedure on the same date or day before the date of HCPCS code G0378.”

“If the composite is not applicable, payment for HCPCS code G0379 may be made under APC 0604. In general, this would occur when the units of observation reported under HCPCS code G0378 are less than eight and no services with a status indicator “T” or “V” or Critical Care (APC 0617) were provided on the same day of service as HCPCS code”

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

Federal Register pages 66789 – 66807

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.”*

Both the proposed and final rules contain lengthy discussions regarding the establishment of a national policy to determine the assignment of E/M codes. The rules address 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 these discussions, 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.

In absence of national guidelines, CMS is requiring that all hospital-specific guidelines for reporting visits meet the 11 guideline principles. These principles are described in detail on [Federal Register page 66805](#).

For clinic visits, CMS will require that hospitals continue to use CPT codes to bill for clinic visits, and to distinguish between new and established patient visits. In addition, CMS will no longer recognize consultation codes for payment under the OPSS.

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; and
- Type B ED visits would continue to be paid based on the five Clinic Visit APCs.

For CY 2008, in some cases when high-level visits are reported with a new or established patient Level 5 CPT E/M code, a Level 4 or 5 emergency department visit CPT code, a critical care CPT code, or direct admission to observation HCPCS code in association with 8 or more hours of non-surgical observation services, CMS will provide a single payment in CY 2008 for the encounter through one of two new composite APCs:

- APC 8002 (Level I Extended Assessment and Management); or
- APC 8003 (Level II Extended Assessment and Management).

See “Encounter-Based and Episode-Based Payments Under the OPSS”, Section II for a complete description of this composite APC payment policy.

Partial Hospitalization

[Federal Register pages 66670 – 66677](#)

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% 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.”*

CMS Final Rule: CMS has adopted the above proposal as final.

For CY 2008, CMS has mitigated the reduction to the partial hospitalization APC payment rate to 50% of the difference between the current APC amount (\$233) and the computed amount based on the PHP data (\$172), resulting in an APC median cost of \$203.

CMS will 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.

In addition, for the CY 2009 OPPS update, CMS is exploring proposing conditions of participation for CMHCs to establish minimum standards for patient rights, physical environment, staffing, and documentation requirements. CMS is also considering changes that are necessary to regulations and claims processing systems to deny payment for low intensity days. CMS is seeking comments on this issue.

Brachytherapy Payment

Federal Register pages 66779 – 66787

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.”

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

CMS is required by law to pay for stranded and non-stranded sources through different payment groups. For CY 2008, CMS will set the median cost for stranded sources at the 60th percentile of the aggregate claims data for the predecessor code for this source. For non-stranded sources, CMS will set the median cost at the 40th percentile of the aggregate claims data for the predecessor code for this source.

The final brachytherapy source HCPCS codes, APC assignments, status indicators, and median costs are available in Table 37 (*Federal Register* page 66785).

Inpatient-Only Procedures Payment

Federal Register pages 66815 – 66817

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.”

CMS Final Rule: CMS has adopted the above proposal as final with no revisions.

CMS will present data regarding CPT codes 20660 and 64818 to the APC Panel at its winter 2008 meeting. At the September 2007 meeting, CMS did not have additional new data available for CPT code 20660 for the APC Panel to consider.

Table 46 (*Federal Register* page 66816) shows the 13 procedures to be removed 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

Federal Register pages 66743 – 66749

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.”

CMS Final Rule: “After consideration of the public comments received, we are finalizing a modified policy for certain procedures involving partial credit for a replacement device.”

“Specifically, we will reduce the payment for an implantation procedure assigned to APCs listed in Table 25, . . . by one half of the device offset that would be applied if a replacement device were provided at no cost or with full credit, if the credit is 50 percent or more of the replacement device cost. We will recognize the new modifier “FC” for reporting these cases”

“Beneficiary copayment will be based on the reduced payment amount.”

For the final rule, CMS is increasing the threshold to which the partial credit reduction policy will apply to cases involving a 50% credit (proposed at 20%) or more toward the total cost of the replacement device. To report receiving a partial credit of 50% or more of the cost of a replacement device, hospitals must either:

1. submit the claims immediately without the HCPCS modifier signifying partial credit for a replacement device and submit a claim adjustment with the HCPCS modifier at a later date once the credit determination is made; or
2. hold the claim until a determination is made on the level of credit.

Table 25 ([Federal Register pages 66748 – 66749](#)) 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. If the APC to which the procedure code is assigned is one of the APCs listed in Table 25, the unadjusted payment rate for the procedure will be reduced by an amount equal to the percent in Table 25 for partial credit device replacement multiplied by the unadjusted payment rate.

As noted in the final decision above, CMS is implementing the adjustment through the use of an appropriate modifier (modifier “FC”). 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 replaced with partial credit under warranty, recall, or field action is one of the devices in identified in Table 26 on [Federal Register page 66749](#). Claims containing the “FC” modifier will not be accepted unless the modifier is on a procedure code with status indicator “S,” “T,” “V,” or “X.”

Critical Access Hospitals (CAHs)—Necessary Provider CAHs

[Federal Register pages 66877 – 66882](#)

Background: 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% 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 put an end to states' authority to waive the location requirement for a CAH by certifying CAHs as necessary providers, 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 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 . . .”

CMS Final Rule: CMS has adopted all of the above proposals as final.

For the final rule, CMS has modified the proposed regulation text to exclude RHCs from the list of provider-based facilities that must comply with the adopted requirements; correct the date references to "on or after January 1, 2008" in cases where it read "after January 1, 2008"; and add the words "off-campus" before the words "provider-based locations" to conform these references to the preamble language.

In addition, CMS states that they recognize that a number of CAHs have plans underway to build or acquire provider-based facilities that will not be completed before January 1, 2008. CMS' regional offices will evaluate these issues on a case-by-case basis.

Hospital Conditions of Participation (CoPs)

Federal Register pages 66882 – 66886

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.

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 Final Rule—Medical History and Physical Examination: CMS has adopted the above proposal as final with no revisions.

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.”*

CMS Final Rule—Post-Anesthesia Evaluation: *“After consideration of the public comments and a further review of the current standards of anesthesia care, . . . we have revised the proposed requirements for the post-anesthesia evaluation . . .”*

“We are requiring that the post-anesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services, and that the post-anesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.”