



WISCONSIN HOSPITAL
ASSOCIATION

**SUMMARY OF THE PROPOSED
CY 2005 MEDICARE
HOSPITAL OUTPATIENT RULE**

September 2004

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SUMMARY OF THE 2005 MEDICARE PROPOSED RULE FOR OUTPATIENT PROSPECTIVE PAYMENT

The Centers for Medicare and Medicaid Services (CMS) published proposed regulations for the Medicare Outpatient Prospective Payment System (OPPS) in the August 16 *Federal Register*. Changes are scheduled to be effective for services on or after January 1, 2005. Comments must be received no later than 5 p.m. on October 8. One original and two copies of comments may be delivered to:

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Alternatively, comments (an original and two copies) may be hand delivered to CMS at:

Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

OR

7500 Security Boulevard
Baltimore, MD 21244-1850

If using the Baltimore address, you must call (410) 786-7195 in advance to schedule the delivery.

Comments may also be submitted electronically to <http://www.cms.hhs.gov/regulations/ecomments>. CMS recommends the attachments to be in Microsoft Word, however, will also accept Excel or WordPerfect documents.

This document summarizes the changes proposed in the 2005 OPPS rule. Where *Federal Register* page numbers are provided, they refer to the August 16, 2004 *Federal Register*. The proposed rule is available online at http://www.wha.org/financeAndData/pps_outpatient.aspx.

I. AMBULATORY PAYMENT CLASSIFICATION (APC) PAYMENTS

CONVERSION FACTOR (*Federal Register* page 50541)

The proposed rule increases the conversion factor by 4.6% from \$54.561 to \$57.098. The increase is based on a market basket update of 3.3%, with a 1.001 adjustment for budget neutrality and an additional increase due to a reduction in the carve-out for pass-through payments from 1.3% in 2004 to 0.13% in 2005.

WAGE INDEX ADJUSTMENT (*Federal Register* page 50541)

The proposal incorporates the inpatient wage index from the proposed inpatient PPS rule, including redefined wage areas and an occupational mix adjustment. Consistent with prior years, the labor-related portion of OPSS payment rates is 60%. CMS specifies that the following provisions of the inpatient PPS rule will also apply to the outpatient PPS:

- an out-migration adjustment to the wage index based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index,
- a three-year transition for urban hospitals that become rural under the new definitions that will allow them to maintain their assignment to the urban areas where they are currently located, and
- application of the special one-time wage index reclassifications granted under Section 508 of the MMA to the outpatient PPS.

CMS indicates that the final inpatient wage index will be used in the outpatient final rule. However, CMS does not mention the one-year temporary relief that was provided in the inpatient final rule for hospitals harmed by the redefinition of wage areas. Under this relief, hospitals experiencing a wage index decrease due to labor market changes receive a blend of 50% of the wage index based on the new definitions and 50% based on the old boundaries. We will ask for clarification to ensure that this relief is also provided for outpatient payment.

OUTLIER PAYMENTS (*Federal Register* page 50542)

CMS is proposing a major change in the outlier methodology to target payments to complex, expensive procedures. The CMS proposal is in response to a Medicare Payment Advisory Commission (MedPAC) analysis reporting that 50% of OPSS outlier payments in CY 2004 were for 21 common services that had relatively low payment rates, such as plain film x-rays and pathology services. CMS believes that the outlier policy is intended to compensate for unusually high cost cases and not for high volume, lower cost services.

In 2004, outlier payments are provided if the cost for a service exceeds 2.6 times the Ambulatory Payment Classification (APC) rate. For 2005, CMS proposes to require that costs must exceed 1.5 times the APC payment rate and also exceed a \$625 fixed dollar threshold. This would eliminate outlier payments for low cost services and provide higher outlier payments for relatively expensive procedures. When the cost of a hospital outpatient service exceeds these thresholds, CMS would pay 50 percent of the amount by which the cost of furnishing the service exceeds 1.5 times the APC payment rate as an outlier payment.

CMS states that the new methodology will continue to pay 2% of total OPSS payments as outliers. CMS does not provide details of this estimate. However, in the Federal Fiscal Year (FFY) 2005 proposed inpatient PPS rule, CMS suggested a substantial increase in the outlier threshold based on inflated charge estimates that did not take into account the charge decreases that many hospitals implemented in 2003 and

2004. In 2003, CMS issued a rule requiring the use of more up-to-date data when determining a hospital's cost-to-charge ratio (CCR) – specifically, a hospital's most recent final or tentatively settled cost report. It also instructed fiscal intermediaries, in certain situations, to retrospectively reconcile outlier payments when a hospital's cost report is settled. As a result of these changes, many hospitals decreased their charges and the overall rate of increase declined. CMS lowered its proposed increase in inpatient outlier threshold based on comments by WHA and the American Hospital Association (AHA) regarding the inflated charge estimates. We will comment on this issue to ensure that CMS is not similarly inflating charges in setting the OPPS outlier threshold.

DEFAULT CCRS (*Federal Register* page 50527)

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. These include new hospitals, hospitals that have a CCR that falls outside predetermined floor and ceiling thresholds, or hospitals that have recently given up their all-inclusive rate status. Currently, CMS uses 1996 and 1997 cost reports to calculate statewide urban and rural CCRs to use as a default.

CMS is proposing to update the default CCRs for CY 2005 based on the most recent available cost reports (2002 cost reports for most hospitals). Under the proposal, some areas would experience a decrease in the default CCR. The lower CCRs would result in decreased payments for hospitals using the default.

The decrease in ratios is caused by the fact that charges were increasing faster than costs during the period between 1996 and 2002. As noted above, charges increased at a much lower rate after 2003. We will comment that the default CCRs should take this into account. In addition, the default CCRs often result in inequitable payments for hospitals that have recently given up their all-inclusive rate status. We will request that CMS instruct intermediaries to work with these hospitals to determine CCRs that will provide an accurate estimate of costs.

TRANSITIONAL CORRIDOR PAYMENTS (*Federal Register* page 50530)

When the OPPS was implemented, transitional corridor payments were established to provide partial relief to hospitals that are receiving less in payments under the OPPS methodology than they 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 decrease compared to the prior payment system. Other hospitals were eligible for partial relief. Transitional corridor payments for most hospitals expired on December 31, 2003. The MMA extended hold-harmless payments through December 31, 2005, for rural hospitals with 100 or fewer beds. It also provided hold-harmless payments during the same period for sole community hospitals located in rural areas. Cancer hospitals and children's hospitals are permanently held harmless.

NEW AND DELETED PROCEDURE CODES (*Federal Register* page 50531)

Every year, CMS modifies the OPPS to incorporate new Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes and to delete codes that are no longer valid. In the past, CMS has permitted a 90-day grace period after implementation of new codes to give providers time to incorporate new codes in their coding and billing systems and to remove the discontinued codes. However, the Health Insurance Portability and Accountability Act (HIPAA) transaction and code set rules require usage of the medical code set that is valid at the time that the service is provided. Therefore,

effective January 1, 2005, CMS is eliminating the 90-day grace period for billing discontinued HCPCS codes.

RECALIBRATION OF APC WEIGHTS (*Federal Register* page 50473)

CMS calculated the APC weights for 2004 using claims for services furnished from April 1, 2002 through December 31, 2002. For CY 2005 the APC weights are calculated based on the most recent available claims data for services furnished on or after January 1, 2003 and before January 1, 2004.

APC Groups

The 2005 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 Current Procedural Terminology (CPT) codes, changes in technologies, new services, and new cost data. In addition, the rule includes input from the Advisory Panel on APC Groups, an outside panel of experts established as required by the Balanced Budget Act (BBA) of 1997.

APCs for Services Other than Pass-Throughs
Number of APC Groups by Category

<u>APC Category</u>	<u>Status Code</u>	<u>2004</u>	<u>2005 Proposed</u>
Medical Visits	V	6	6
Surgical Procedures	T	203	208
Significant Procedures	S	123	126
Ancillary Services	X	43	43
Drugs/Biologicals	K	251	294
Partial Hospitalization	P	1	1
New Technology	S/T	74	74
Total		701	752

The most significant CY 2005 changes affect the APCs for drugs, biologicals, and radiopharmaceuticals. The MMA substantially changed the payment methodology for many of these items. As a result, the CY 2005 proposed rule establishes new payment categories for some drugs and substantially changes the payment rates for many drugs, biologicals, and radiopharmaceuticals.

II. TRANSITIONAL PASS-THROUGH PAYMENTS (*Federal Register* page 50502)

The Balanced Budget Refinement Act of 1999 (BBRA) provided transitional pass-through payments for certain drugs, pharmaceuticals, biologicals, and medical devices. Under the proposal, the number of drugs and devices paid as pass-throughs would decrease as shown below.

<u>APC Category</u>	<u>Status Code</u>	<u>2004</u>	<u>2005 Proposed</u>
New Drugs and Biologicals	G	22	19
Medical Devices	H	9	3
Total		31	22

The aggregate amount of pass-through payments cannot exceed 2.0% of total OPSS payments. However, CMS estimates that payments for the proposed pass-throughs will only equal 0.13% of total OPSS payments. Therefore, CMS proposes to reduce the amount that is carved-out of the conversion factor for pass-throughs.

The reduced carve-out is due to a CMS determination that the proposed pass-through amount for drugs equals zero for CY 2005. CMS is proposing to make separate payment for new drugs and biologicals based on the Average Sale Price (ASP) plus six percent whether or not the drug is granted pass-through status. According to CMS, the pass-through for drugs is equal to the additional amount that will be paid above the otherwise applicable fee schedule amount. Therefore, there is no carve-out for new drug and biological pass-through payments.

Payment for Pass-Through Devices (*Federal Register* page 50501)

CMS has not identified any new pass-through devices for CY 2005. Three devices designated as pass-throughs in CY 2004 will retain that status. The following devices will continue to be paid on a cost basis in CY 2005:

C1814 Retinal tamponade device, silicone oil
C1818 Integrated keratoprosthesis
C1819 Tissue localization excision device

Payment for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals (*Federal Register* page 50503)

In CY 2004 and prior years, new drugs and biologicals that were granted pass-through status were paid at 95% of the Average Wholesale Price (AWP). The MMA provided that pass-through drugs would be paid at 85% of AWP in 2004 and Average Sales Price (ASP) plus six percent in 2005 and thereafter. The ASP drug payment system is based on data submitted by manufacturers. In 2005, it will apply to most Medicare Part B drugs not paid on a cost or prospective payment basis including payments under the physician fee schedule and some payments under the OPSS.

There are 13 drugs that had pass-through status in CY 2004 that will still be eligible for pass-through payment in CY 2005. Rates for eight of these will decrease due to the change in the payment methodology. Another five drugs were granted pass-through status for the first time in CY 2005.

See Table 1 which contains a complete list of the "Proposed Drugs and Biologicals with Pass-Through Status in CY 2005."

EXPIRATION OF PASS-THROUGH PAYMENT (*Federal Register* page 50500)

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

Expiring Pass-through Devices: CMS proposes to retire six devices from pass-through status after December 31, 2004. In 2005, these items will be treated as packaged items with no separate payment provided. Instead, the cost for these devices will be incorporated into the rates of associated procedure APCs. The following devices will no longer be paid as pass-throughs in CY 2005:

C1888 Catheter, ablation, non-cardiac, endovascular (implantable)
C1900 Lead, left ventricular coronary venous system
C1783 Ocular implant, aqueous drainage assist device
C1884 Embolization protective system
C2614 Probe, percutaneous lumbar discectomy
C2632 Brachytherapy solution, iodine-125, per mC

Expiring Pass-through Drugs: The CMS proposal includes 13 drugs whose pass-through status will expire on December 31, 2004. These drugs are:

J0583 Injection, Bivalirudin, per 1 mg (trade name: Angiomax Injection)
C9112 Injection, Perflutren lipid microsphere, per 2 ml (trade name: Definity)
C9113 Injection, Pantoprazole sodium, per vial (trade name: Protonix)
J1335 Injection, Ertapenem sodium, per 500 mg (trade name: Invanz)
J2505 Injection, Pegfilgrastim, per 6 mg single dose vial (trade name: Neulasta)
J9395 Injection, Fulvestrant, per 25 mg (trade name: Faslodex)
C9121 Injection, Argotroban, per 5 mg (trade name: Acova)
C9200 Orcel, per 36 square centimeters (trade name: Orcel)
C9201 Dermagraft, per 37.5 square centimeters (trade name: Dermagraft)
J2324 Nesiritide, per 0.5 mg (trade name: Natrecor)
J3315 Injection, Triptorelin pamoate, per 3.75 mg (trade name: Trelstar depot Trelstar LA)
J3487 Injection, Zoledronic acid, per 1 mg (trade name: Zometa)
Q0137 Injection, Darbepoetin Alfa, 1 mcg, non-ESRD use (trade name: Aranesp)

III. PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS WITHOUT PASS-THROUGH STATUS

The MMA mandated a number of changes in payment policies for drugs, biologicals, and radiopharmaceuticals. As a result, the number of drugs, biologicals, and radiopharmaceuticals with a distinct APC rate increased from 251 in CY 2004 to 294 in CY 2005. The payment rates for many of these items also changed significantly. There were 247 drugs, biologicals, and radiopharmaceuticals that had APC rates in both CY 2004 and CY 2005. The rates for 162 of these APCs decreased from CY 2004 to CY 2005, rates for 60 increased, and there was no change in the payment rate for 25 of these APCs.

Packaged Drugs, Biologicals and Radiopharmaceuticals (*Federal Register* page 50505)

Drugs are generally packaged into the rate for other procedures or services unless they are determined to be relatively expensive or are rarely used. Packaged items are not separately paid. Some items such as single indication orphan drugs, certain vaccines, and blood and blood products are excluded from the packaging policy. The MMA requires that the threshold for establishing separate rates for drugs and biologicals be set at \$50 per administration for CYs 2005 and 2006. This is consistent with the threshold that CMS applied in CY 2004. CMS is implementing this policy and proposes to package the cost of drugs, biologicals, and radiopharmaceuticals whose median cost per day is less than \$50 into the procedures with which they are billed.

Payment for “Specified Covered Outpatient Drugs” (*Federal Register* page 50506)

The MMA establishes a class of drugs called “specified covered outpatient drugs”. These are defined as any existing APC that is a drug, biological, or radio pharmaceutical agent for which payment was made on a pass-through basis on or before December 31, 2002. Pass-through status for these drugs has expired and they are currently paid through the APC rates. The MMA requires that payment for these drugs be

based on the AWP. Payments are determined based on three categories: sole source, innovator multiple source, and non-innovator multiple source. Effective January 1, 2004, payments for these categories were subject to varying floors and ceilings.

Sole Source Drugs: Sole source drugs require no Food and Drug Administration (FDA) approval since they are considered brand name drugs. In 2004, sole source drugs could be paid no less than 88% and no more than 95% of the AWP. Implementation of the 88% AWP payment floor resulted in a rate increase for the majority of sole source drugs compared to CY 2003. In CY 2005, the floor for these drugs will decrease to 83% of the AWP while the ceiling will remain at 95% of the AWP. As a result, 118 out of 138 of these drugs will experience a rate decrease in CY 2005.

See Table 2 which contains the “Proposed OPSS Payment Amounts for Sole Source Drugs, Biologicals, and Radiopharmaceuticals for CY 2005.”

Multiple Source Drugs: CMS has identified two categories of multiple source drugs: innovator multiple source and non-innovator multiple source drugs. Innovator multiple source drugs are drugs that were originally sole source drugs for which FDA approved generic alternatives. In both CY 2004 and CY 2005, payments for innovator multiple source drugs are limited to the lower of the payment rate calculated under CMS’ standard median cost methodology or 68% of the AWP. Non-innovator multiple source drugs are generic drugs, not considered to be innovator multiple source drugs, which are approved by FDA. Non-innovator multiple source drugs will be paid the lower of the payment rate calculated under CMS’ standard median cost methodology or no more than 46% of the AWP in both CY 2004 and CY 2005. Implementation of the ceilings caused the majority of payment rates for multiple source drugs to decrease from CY 2003 to CY 2004. In CY 2005, 21 out of 62 multiple source drugs will be held to the ceiling and experience no rate change.

See Table 3 which contains the “Proposed OPSS Payment Amounts for Innovator and Noninnovator Multiple Source Drugs, Biologicals, and Radiopharmaceuticals for CY 2005.”

Payment for New Drugs and Biologicals Prior to Assignment of HCPCS Codes (*Federal Register* page 50516)

After a drug is approved by the FDA, a period of time passes before it is assigned a HCPCS code and it becomes eligible for pass-through payment. Currently, hospitals are instructed to bill for drugs without HCPCS codes using a general code for unlisted or unclassified drugs. There is no payment for these drugs, and the reported charges are included on the claim as packaged services. The MMA requires that outpatient drugs and biologicals for which a HCPCS code has not been assigned be paid at 95% of the AWP. This provision was effective January 1, 2004 but was not implemented because CMS had not yet determined a methodology for billing these drugs.

CMS adopted an interim approach through a program transmittal issued on May 28, 2004. The transmittal instructed hospitals to bill for a drug or biological that is newly approved by the FDA by reporting the National Drug Code (NDC) for the product along with the HCPCS code C9399: Unclassified drug or biological. When C9399 appears on a claim, it is suspended for manual pricing by the fiscal intermediary. The fiscal intermediary prices the claim at 95% of its AWP. CMS proposes to make this payment methodology permanent and to expand to include payment for new radiopharmaceuticals to which a HCPCS code is not assigned. CMS is requesting comments on hospital experiences using this approach and possible alternatives.

Payment for New Drugs and Biologicals with HCPCS Codes and without Pass-Through Status
(*Federal Register* page 50514)

The MMA does not address payments for new drugs and biologicals that do not meet the criteria for pass-through payments or that do not have a reference AWP. There is no data in the outpatient claims file for the first two years after a drug is approved by the FDA. Therefore rates cannot be established using the standard methodology. Currently, CMS packages payment for these new drugs and biologicals until there is sufficient claims data to calculate rates. However, CMS is concerned that some of these new drugs and biologicals may be expensive, and packaging them may jeopardize beneficiary access. In addition, CMS does not want to delay separate payment for a new drug or biological solely because a pass-through application was not submitted.

Therefore, in CY 2005, CMS is proposing to pay for new drugs and biologicals which do not have pass-through status at the ASP plus six percent. This is the same methodology that would be used to calculate the OPSS payment for pass-through drugs and biologicals in CY 2005. CMS notes that treating new drugs and biologicals the same, irrespective of whether pass-through status has been granted may discourage manufacturers from applying for pass-through payment. However, CMS indicates that a pass-through application expedites the assignment for HCPCS codes and establishment of a payment rate for new drugs. Therefore, CMS encourages manufacturers to continue to apply for pass-through status.

See Table 4 which contains the “List of Drugs and Biologicals Not Eligible for Pass-Through Status and Proposed for Separate Nonpass-Through Payment.”

Orphan Drugs (*Federal Register* page 50517)

Orphan drugs are generally expensive drugs that by definition are rarely used. CMS has recognized that packaging these drugs would result in insufficient payment to cover their cost. Therefore, CMS makes a separate payment for these drugs. CMS designated 12 orphan drugs in CY 2004 and set the rates based on 88% of the AWP for 10 of them, and on 94% of the AWP for the other two.

CMS proposed to continue separate payment for the 12 orphan drugs and has not identified any additional orphan drugs for CY 2005. CMS is proposing to pay for orphan drugs at the higher of 88% of the AWP or 106% of the ASP. However, payment would be capped at 95% of AWP, which is the upper limit allowed for sole source specific covered outpatient drugs.

Vaccines (*Federal Register* page 50517)

In CY 2003, CMS established payment for influenza (flu) and pneumococcal pneumonia (PPV) on a reasonable cost basis. This was in response to concerns about yearly fluctuations in the cost of the flu vaccine. CMS is proposing to continue paying for influenza and pneumococcal pneumonia vaccines under the reasonable cost methodology in CY 2005.

Payment for Blood and Blood Products (*Federal Register* page 50521)

Payment for blood and blood products under OPSS have been made through separate payment in APCs rather than packaging them into payment for the procedures with which they were administered. Since the implementation of OPSS, payment for blood was established based on external data due to limited Medicare claims data. In addition, rate decreases for blood products were subject to limits in CY 2003 and payments were frozen at the CY 2003 level in CY 2004. In general, CMS prefers the use of Medicare claims data when setting payment rates but has had problems establishing blood product rates.

For CY 2005, CMS is proposing to continue to pay separately for blood and blood products, and establish new APCs that would allow each blood product to be in its own separate APC. CMS determined that several of the blood product APCs contained multiple blood products with no clinical homogeneity or whose product-specific median costs may not have been similar and therefore, is proposing to reassign some of these HCPCS already contained in certain APCs to new APCs.

CMS conducted an analysis to look at the billing of blood and blood products as well reporting of costs and charges in cost centers specific to blood on hospitals cost reports. CMS experienced problems with the CCRs used to adjust claim charges to costs for blood and blood products. However, CMS has developed a methodology **to set payment rates for all blood and blood products based on CY 2003 claims data, utilizing an actual or simulated hospital blood-specific CCR to convert charges to costs.**

CMS noticed that in applying this new methodology, simulated median costs used to set payment rates for procedures relying on a low volume of blood units less than 1000 had large decreases compared to CY 2004. Therefore, **CMS is proposing to increase the sample size and combine claims data for CY 2002 and 2003 to set payment rates for low-volume blood and blood products.**

Overall, payment rates for blood and blood products increase under the CMS proposed methodology. Six of the nine payment rates decreasing in CY 2005 are the low volume blood products.

See Table 5 which contains the “Proposed Assignment of Blood and Blood Product Codes to APCs for CY 2005” and the “Low Volume Proposed Blood and Blood Product Codes for CY 2005 Payments.”

Payments for Other Drugs (*Federal Register* page 50514)

The Law does not specify the payment methodologies for separately payable drugs and biologicals that never received pass-through status and that are not otherwise addressed in the categories described above. Drugs for which payment is not specified include: those that have been paid separately since implementation of the OPSS on August 1, 2000, but are not eligible for pass-through status, and those that have historically been packaged with the procedure with which they are billed but, based on the CY 2003 claims data, their median cost per day is above the \$50 packaging threshold. CMS is proposing to set payment rates for these drugs based on claims data using the standard methodology for determining APC rates. This is consistent with prior CMS policy regarding these drugs.

IV. APC GROUP CHANGES

REASSIGNMENT OF NEW TECHNOLOGY CODES TO CLINICALLY APPROPRIATE APCs (*Federal Register* page 50465)

In 2002, CMS added “new device technology” APCs to cover devices that were not represented in the 1996 base year data, but did not meet the transitional payment pass-through criteria. Procedures are assigned to new technology APCs until enough data are collected to allow assignment to clinically appropriate APCs. In CY 2005, CMS has identified 24 procedures that were assigned to new technology APCs that now have adequate data to support assignment into specific clinical APCs. This reassignment will cause a decrease in APC payments for 17 of the 24 procedures.

See Table 6 which contains the “Proposed APC Reassignment of New Technology Procedures Into Clinical APCs.”

In addition, CMS indicates that a number of positron emission tomography (PET) scans currently classified into New Technology APC 1516 have sufficient data for assignment to clinical APCs.

However, this will reduce payments for PET scans and CMS is concerned that this might hinder beneficiary access to this technology. Therefore, CMS is considering three options as the proposed payment PET scans in CY 2005:

- Option 1: Continue in CY 2005 the current assignment of the scans to New Technology APC 1516 prior to assigning to a clinical APC. APC 1516 has a rate of \$1,450.00.
- Option 2: Assign the PET scans to a clinically appropriate APC priced according to the median cost of the scans based on CY 2003 claims data. Under this option, PET scans would be assigned to APC 0420: PET imaging, with a rate of \$898.64.
- Option 3: Transition assignment to a clinical APC in CY 2006 by setting payment in CY 2005 based on a 50-50 blend of the median cost and the CY 2004 New Technology. We would assign the scans to New Technology APC 1513 for payment with a rate of \$1,115.00.

CMS is requesting comments on these payment options.

PAYMENT FOR DRUG ADMINISTRATION AND CHEMOTHERAPY (*Federal Register* page 50519)

The following HCPCS codes are currently used for drug administration payments:

Q0081 Infusion therapy other than chemotherapy
Q0083 Chemotherapy by other than infusion
Q0084 Chemotherapy by infusion
Q0085 Chemotherapy by both infusion and other

The payment for these procedures includes the cost of certain drugs that are packaged into the rate. When a hospital administers a drug packaged with a procedure, CMS believes that the hospital receives the appropriate reimbursement. However, these procedure codes are also billed when a hospital administers a separately payable drug. CMS believes this results in an overpayment because the hospital is paid for the drug that is separately billed as well as the procedure that includes some cost for packaged drugs.

In CY 2004 CMS proposed to change coding and payment for these services to enable them to pay more accurately for the wide range of services and the drugs that they package into these per visit codes. However, it was not implemented but CMS had stated that they would consider it for CY 2005. In the CY 2005 proposed rule CMS is proposing to replace the Q codes with CPT codes for drug administration but to crosswalk the CPT codes into APCs that reflect how the services would have been paid under the Q codes.

****See Table 7 which contains the “Proposed Crosswalk from CPT Codes for Drug Administration to Drug Administration APCs.”****

If CMS adopts the CPT codes for drug administration to ensure accurate payment in the future, it would be critical for hospitals to bill the charges for the packaged CPT codes for drug administration for CY 2005, even though there would be no separate payment for them in CY 2005. A hospital's CY 2005 claims data will be the basis for its CY 2007 OPPS payments.

DEVICE-DEPENDENT APCs (*Federal Register* page 50490)

CMS is proposing to limit payment decreases for 43 “device-dependent” APCs. These are APCs for services that CMS has determined cannot be provided without an associated medical device. They include procedures such as insertion of a pacemaker, diagnostic cardiac catheterization, and brachytherapy. Many of these devices were formerly paid as pass-throughs but are now packaged into the procedure APC.

In 2003, the pass-through status of many new technology devices expired. These devices were packaged into the payment for the primary procedure or service with which they are associated. At that time, CMS deleted the Healthcare Common Procedure Coding System (HCPCS) codes that were used to code these devices. Hospitals no longer received separate payment for these items and were no longer required to report codes for the devices. CMS continued this policy in subsequent years by packaging devices as their pass-through status expired.

CMS has consistently experienced problems in determining payment rates for the procedures that include packaged devices. When APC rates were calculated for these procedures using claims data, the resulting rates were often substantially less than the cost of the device. In CY 2003 and CY 2004, CMS determined that many hospitals were not consistently reporting charges for the devices. Therefore, CMS limited the calculation to claims that reported a separate charge for the device and placed limits on rate decreases for these APCs. The calculation of rates for device-dependent APCs is more problematic in CY 2005. The CY 2005 APC rates are calculated using 2003 claims data and CMS eliminated the HCPCS codes for devices in 2003. This makes it impossible to follow past practice and limit the calculation to claims with device charges.

CMS proposes to determine rates for device-dependent APCs based on the greater of:

- median costs calculated using CY 2003 claims data, or
- 90% of the APC payment median for CY 2004 for such services.

As a result, proposed rates for the device-dependent APCs were limited to a 6.5% decrease. Out of the 43 device-dependent APCs, rates for 13 decreased by 6.5% and rates for 12 decreased by a lesser amount. APC 0048 experienced a decrease greater than 6.5%, however this was caused by a change in the definition for the APC.

See Table 8 which contains the “Proposed Device-Dependent APCs.”

DEVICE CODING (*Federal Register* page 50491)

CMS indicates that the limit on decreases for device-dependent APCs is a transition to the eventual use of claims data to calculate rates using the standard methodology. Therefore, CMS proposes to require that hospitals report individual HCPCS codes on bills for device-dependent APCs. In CY 2005, this would be required only for the APCs where the limit to 90% of CY 2004 payments is applied.

OBSERVATION SERVICES (*Federal Register* page 50532)

In CY 2002, CMS established separate payment for observation services under the OPPS for three medical conditions: chest pain, congestive heart failure, and asthma. A number of accompanying requirements were established, including provision of specific diagnostic tests to beneficiaries based on their diagnoses. CMS has responded comments from the hospital industry and the APC Panel asserting that the requirements for specific diagnostic tests are overly prescriptive and administratively burdensome. As a result CMS proposes that, beginning in CY 2005, **the following tests would no longer be required** to receive payment for APC 0339 (Observation):

- for congestive heart failure, a chest x-ray and electrocardiogram and pulse oximetry;
- for asthma, a breathing capacity test or pulse oximetry;
- for chest pain, two sets of cardiac enzyme tests; either two CPK or two troponins and two sequential electrocardiograms.

CMS is also proposing to change the requirements for counting patient time in observation care. Currently, hospitals report the time in observation beginning with the admission of the beneficiary to observation and ending with the physician's order to discharge the patient from observation. Hospitals have commented that a manual record review is required to capture the time of the physician's orders for discharge. In addition, hospitals may continue to provide specific discharge-related observation care for a short time after the discharge orders are written. In response, CMS is proposing to modify the rules so that time in observation care would end when the outpatient is actually discharged from the hospital or admitted as an inpatient.

CMS provides the following requirements to receive separate payment for "G0244: medically necessary observation services" in CY 2005:

- The beneficiary must have one of three medical conditions: congestive heart failure, chest pain, or asthma. The hospital bill must report an appropriate admitting or principal diagnosis to reflect the condition.
- The hospital must provide and report on the bill an emergency department visit, clinic visit, or critical care on the same day or the day before the separately payable observation care is provided. For direct admissions to observation, in lieu of an emergency department visit, clinic visit, or critical care, code "G0263: admission with CHF, CP, asthma" must be billed on the same day as the observation care.
- "G0244: medically necessary observation services" must be billed for a minimum of 8 hours.
- No procedures with a 'T' status indicator, except the code for infusion therapy of other than a chemotherapy drug can be reported on the same day or day before observation care is provided.
- Observation time must be documented in the medical record and begins with the beneficiary's admission to an observation bed and ends when he or she is discharged from the hospital.
- The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.
- The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.

PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT (*Federal Register* page 50536)

CMS identifies certain procedures that are typically provided only in an inpatient setting. These procedures are assigned a status of "C: inpatient procedure, not payable under the OPPI". Hospitals were advised to admit these patients in order to receive payment. CMS rejected an APC Panel recommendation to eliminate the list of inpatient only procedures. However, CMS did review the current list and has removed several procedures from it.

See Table 9 which contains the "Proposed Procedure Codes to Be Removed From Inpatient List and Proposed APC Assignment"*

PAYMENT FOR BRACHYTHERAPY SOURCES (*Federal Register* page 50539)

The MMA required that all devices of brachytherapy consisting of a seed or seeds (or radioactive source) be paid based on a facility's charges for each device, adjusted to cost. This provision is effective for services furnished from January 1, 2004 through December 31, 2006. In addition, because brachytherapy sources are paid at cost they are excluded from outlier payments and from any budget neutrality requirements.

CMS is proposing modifications to the coding rules for brachytherapy sources and the addition of three new codes.

See Table 10 which contains the “Current and Proposed Separately Payable Brachytherapy Sources”

PAYMENT FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (*Federal Register* page 50540)

In CY 2003, CMS implemented a new modifier: “CA: procedure payable only in the inpatient setting when performed emergently on an outpatient who dies before admission”. This allows payment for outpatient services on a claim that has the same date of service as a procedure that is on the “inpatient only” list. In CY 2004, CMS created APC 0375 to pay for these services. The rate for APC 0375 was set at \$1,150 which was the payment amount for APC 1513: New Technology – Level XIII. CMS now has actual claims data for this APC and proposes to use the standard APC methodology to determine a rate for APC 0375. Using this methodology, CMS has proposed a payment rate of \$2,757.68 for APC 0375 in CY 2005.

ASSIGNMENT OF “UNLISTED” HCPCS CODES (*Federal Register* page 50468)

“Unlisted” codes define a general clinical or procedural category, but they lack the specificity needed to describe the resources used in the service. They are used to report services for which there is no HCPCS code that specifically describes the service and include codes with descriptors such as: “unlisted procedure”, “not otherwise classified,” or “not otherwise specified.”

According to CMS, unlisted codes are assigned to the lowest level, clinically appropriate APC under the Medicare OPSS. This creates an incentive for providers to select the appropriate, specific HCPCS code to describe the service where one is available. In the proposed rule, CMS states that they reviewed the HCPCS code assignments and found a number of unlisted codes that violated this policy. CMS proposes to reassign 22 unlisted HCPCS codes to lower level APCs.

See Table 11 which contains the “Proposed Reassignment of Unlisted HCPCS Codes”

OTHER APC CHANGES (*Federal Register* page 50453)

CMS is proposing to revise several other APCs by reassigning certain HCPCS or CPT codes. CMS believes the revisions assign the procedures to APCs that more accurately reflect resource use or improve clinical homogeneity.

V. GUIDELINES FOR EVALUATION AND MANAGEMENT CODES (*Federal Register* page 50538)

Emergency and clinic visits are paid based on three levels of service: low, mid, and high. The level is determined by the reported emergency and management (E/M) CPT code. There is currently no uniform policy on which E/M code should be used. Instead, each hospital creates a set of internal guidelines for determining the proper level of service. If it develops and follows these guidelines, a hospital is considered in compliance with OPSS coding requirements. In the November 7, 2003 OPSS final rule, CMS discussed plans for uniform coding guidelines and asked for public comment. In this rule, CMS indicates that they are continuing to work on a proposal and have not yet made plans for implementation of uniform coding guidelines. CMS anticipates providing at least 6 to 12 months notice to allow for training and system changes.

VI. PARTIAL HOSPITALIZATION (*Federal Register* page 50543)

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). Payment to providers for partial hospitalization services is based on a per diem payment. CMS proposes to increase the PHP APC per diem amount from \$286.82 in CY 2004 to \$292.19 in CY 2005. The PHP outlier threshold for CY 2005 would be set at 3.35 times the partial hospitalization APC rate and payment would be provided for 50% of the cost over the threshold.