



WISCONSIN HOSPITAL
ASSOCIATION

SUMMARY OF THE FINAL CY 2005 MEDICARE HOSPITAL OUTPATIENT RULE

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SUMMARY OF THE 2005 MEDICARE FINAL RULE FOR OUTPATIENT PROSPECTIVE PAYMENT

The Centers for Medicare and Medicaid Services (CMS) has published its final regulations for the Medicare Outpatient Prospective Payment System (OPPS) in the November 15, 2004 *Federal Register*. Changes are effective for services provided on or after January 1, 2005.

This document summarizes the changes in the final 2005 OPPS rule. Where *Federal Register* page numbers are provided, they refer to the November 15, 2004 *Federal Register*. The final rule is available online at http://www.wha.org/financeAndData/ppps_outpatient.aspx.

I. AMBULATORY PAYMENT CLASSIFICATION (APC) PAYMENTS

CONVERSION FACTOR (*Federal Register* page 65841)

The final rule increases the conversion factor by 4.4% from \$54.561 in CY 2004 to \$56.983 in CY 2005. The increase is based on a marketbasket update of 3.3%, with a .9986 adjustment for budget neutrality and an additional 1.2% increase due to a reduction in the “carve-out” for pass-through payments from 1.3% in 2004 to 0.1% in 2005.

WAGE INDEX ADJUSTMENT (*Federal Register* page 65842)

The final rule adopts the inpatient wage index from the final Inpatient Prospective Payment System (IPPS) rule, including redefined wage areas and an occupational mix adjustment. These wage indexes will also apply to TEFRA hospitals that participate in OPPS, but not in IPPS. Consistent with prior years, the labor-related portion of OPPS payment rates is 60%. The final rule specifically states that the following provisions of the IPPS rule will also apply to the OPPS:

- 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;
- application of all reclassifications, including the special one-time wage index reclassifications granted under Section 508 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.
- a blend of an occupational mix adjusted wage index at 10% of the average hourly wage; and
- adoption of the IPPS temporary, one-year relief provision of a 50/50 blend of old and new wage indexes for hospitals with wage area changes that result in a lower wage index under Core-based Statistical Areas (CBSAs).

OUTLIER PAYMENTS (*Federal Register* page 65844)

CMS is adopting a major change in the outlier methodology to target payments for complex, expensive procedures. This is in response to a Medicare Payment Advisory Commission (MedPAC) analysis reporting that 50% of OPPS 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 APC rate. Per the 2005 final rule, costs must exceed 1.75 times the APC payment rate and exceed the APC rate plus a \$1,175 fixed dollar threshold. This is intended to 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 will pay an outlier payment of 50% of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. CMS had proposed lower threshold values in its proposed rule for 2005, but states that these revised numbers reflect the inclusion of a charge inflation factor of 18.76 percent (to account for estimated charge increases between 2003 and 2005) in the CMS estimates for CY 2005 service costs. CMS used this same inflation factor in its inpatient PPS calculations. CMS estimates that the new methodology will continue to pay 2% of total OPPS payments as outliers.

DEFAULT COST-TO-CHARGE RATIOS (CCRs) (*Federal Register* page 65821)

CMS uses CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS. Default CCRs are used for hospitals that are determined to have invalid CCRs such as new hospitals, hospitals with a CCR that falls outside predetermined floor and ceiling thresholds, or hospitals that have recently given up their all-inclusive rate status. Since the implementation of OPPS, CMS has used 1996 and 1997 cost reports to calculate statewide urban and rural CCRs for use as defaults.

Under the final rule, CMS will update the default CCRs for CY 2005 to be based on the most recent available cost reports (2002 cost reports for most hospitals). The statewide default CCRs are calculated using the same CCRs that are used to adjust charges to costs on submitted claims. Only valid CCRs are used, i.e. CCRs for all-inclusive hospitals, Critical Access Hospitals and other non-OPPS hospitals are excluded and outliers are trimmed. Most areas will experience a decrease in their default CCR – lower CCRs will result in decreased payments for hospitals using the default.

The decrease in default CCRs is caused by charges that were increasing faster than costs during the period between 1996 and 2002. CMS has instructed its fiscal intermediaries to recalculate CCRs as soon as the first full year of Cost Report data becomes available for those all-inclusive hospitals and other hospitals that rely on default CCRs.

TRANSITIONAL CORRIDOR PAYMENTS (*Federal Register* page 65825)

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. The final rule implements these provisions.

NEW AND DELETED PROCEDURE CODES (*Federal Register* page 65828)

Every year, CMS modifies the OPPS to incorporate new Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes and deletes codes that are no longer valid. In the past, CMS had permitted a 90-day grace period after implementation of new codes to give providers time to incorporate the new codes into 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 of discontinued HCPCS codes.

RECALIBRATION OF APC WEIGHTS (*Federal Register* page 65730)

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 final CY 2005 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 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</u>
Medical Visits	V	6	6
Surgical Procedures	T	203	208
Significant Procedures	S	123	123
Ancillary Services	X	43	44
Drugs/Biologicals	K	251	315
Partial Hospitalization	P	1	1
New Technology	S/T	74	74
Total		701	771

The most significant CY 2005 changes are 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 final 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

The Balanced Budget Refinement Act of 1999 (BBRA) provided transitional pass-through payments for certain drugs, pharmaceuticals, biologicals, and medical devices. Per the final CY 2005 OPSS rule, the number of drugs and devices paid as pass-throughs will change as shown below:

APC Category	Status Code	2004	Expirations	Additions	Net 2005
New Drugs and Biologicals	G	25	12	10	23
Medical Devices and Cost-based Brachytherapy Sources	H	16	5	3	14
Total		41	17	13	37

The net increase in transitional pass-through payment APCs reflects the expiration of some payments and the inclusion of new payments. 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 0.1% of total OPSS payments. Therefore, CMS has reduced the amount that is carved out of the conversion factor for pass-throughs. This estimate includes the determination by CMS that the proposed pass-through amount for drugs equals zero for CY 2005. Per the MMA, CMS will be making separate payments for new drugs and biologicals based on the Average Sale Price (ASP) plus 6%, 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 65771)

Three devices designated as pass-throughs in CY 2004 will retain their status in CY 2005:

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

In addition, three new code H's, all brachytherapy sources, have been identified for cost-based payment (see discussion on brachytherapy on page 11).

PAYMENT FOR PASS-THROUGH DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS (*Federal Register* page 65776)

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 provides that pass-through drugs be paid at 85% of AWP in 2004 and ASP plus 6% in 2005 and thereafter. The ASP drug payment system is based on data submitted by manufacturers. In 2005, this 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.

Thirteen drugs had pass-through status in CY 2004 and are still be eligible for pass-through payments in CY 2005. Rates for ten of these drugs will decrease due to the change in the payment methodology. Ten drugs have been granted pass-through status for the first time in CY 2005.

EXPIRATION OF PASS-THROUGH PAYMENTS

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 (*Federal Register* page 65771): CMS is retiring five devices from pass-through status after December 31, 2004. These items will be treated as packaged items, with no separate payment, in CY 2005. Instead, the cost for these devices will be incorporated into the rates of the associated procedure APCs. A sixth pass-through device, HCPCS Code C2632: Brachytherapy solution has been retired from pass-through status, but remains as a Code H with cost-based payment. 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

Expiring Pass-through Drugs (*Federal Register* page 65776): The final rule lists 12 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)

Table 22 of the Federal Register also lists a thirteenth pass-through expiration for HCPCS code Q0137; however, this drug was not identified as having pass-through status in 2004.

Three of these drugs: J9395; C9121 and J3315, will be paid as "specified covered outpatient drugs" effective January 1, 2005.

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 315 in CY 2005, as many drugs were unpackaged from other APCs. The payment rates for many of these items have changed significantly. There were 247 drugs, biologicals, and radiopharmaceuticals that had APC rates in both CY 2004 and CY 2005. The rates for 164 of these APCs decreased from CY 2004 to CY 2005, the payment rates for 60 APCs increased and there was no change in the payment rate for 23 of these APCs.

PACKAGED DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS (*Federal Register* page 65779)

Costs for 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. The MMA requires that the threshold median cost for establishing separate rates for drugs, biologicals and radiopharmaceuticals be set at \$50 per administration for CYs 2005 and 2006 – this is consistent with the threshold that CMS established in 2004. The final CY 2005 rule implements this policy, with an exception for drugs, biologicals and radiopharmaceuticals with costs that were above the threshold in 2004, but below in 2005; they will continue to receive separate payment in 2005.

PAYMENT FOR “SPECIFIED COVERED OUTPATIENT DRUGS” (*Federal Register* page 65781)

The MMA establishes a class of drugs called “specified covered outpatient drugs.” These are defined as any existing covered outpatient drug, biological, or radiopharmaceutical agent for which a separate APC exists and (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 has expired and, hence, they are currently paid non-pass-through APC rates. The MMA requires that payment for these drugs be based on a reference AWP.

Specified covered outpatient drugs are grouped into 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. Three drugs with pass-through status that expires in 2005: J9395; C9121 and J3315, are now listed by CMS as specified covered outpatient drugs.

Sole Source Drugs: Sole source drugs are, generally, brand name drugs with no approved generic counterpart. 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 rate increases for the majority of sole source drugs when 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, 120 out of 130 sole source drugs will experience a rate decrease in CY 2005.

Multiple Source Drugs: The two categories of multiple source drugs are: innovator multiple source drugs and non-innovator multiple source drugs. Innovator multiple source drugs are drugs that were originally sole source drugs for which the Food and Drug Administration (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 the CMS standard median cost methodology or 68% of the AWP. Non-innovator multiple source drugs are generic drugs, not considered innovator multiple-source drugs, which are approved by the FDA. Non-innovator multiple source drugs are paid the lower of the payment rate calculated under the CMS standard median cost methodology or no more than 46% of the AWP in both CY 2004 and CY 2005. Implementation of these ceilings had caused the majority of payment rates for multiple source drugs to decrease in CY 2004. In CY 2005, 16 out of 58 eligible multiple source drugs will be held to the ceiling and, hence, experience no rate change.

PAYMENT FOR NEW DRUGS AND BIOLOGICALS PRIOR TO ASSIGNMENT OF HCPCS CODES (*Federal Register* page 65804)

After a drug has been approved by the FDA, a period passes before it is assigned a HCPCS code and 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 established 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 at that time because CMS had not yet determined a methodology for billing these drugs.

CMS adopted an interim approach in May, 2004 and 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 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. The final CY 2005 rule makes this payment methodology permanent and expands it to include payment for new radiopharmaceuticals for which a HCPCS code is not assigned.

PAYMENT FOR NEW DRUGS AND BIOLOGICALS WITH HCPCS CODES AND WITHOUT PASS-THROUGH STATUS (*Federal Register* page 65797)

The MMA does not address payments for new drugs and biologicals that do not meet the criteria for pass-through payments or do not have a reference AWP. There are no data in the outpatient claims file for the first two years after a drug is approved by FDA. Therefore, rates cannot be established using the standard methodology. Currently, CMS packages payment for these new drugs and biologicals into a related APC 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 that 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 will pay for new drugs and biologicals that do not have pass-through status according to the same methodology established under the Medicare Physicians' Fee Schedule, i.e. 106% of the ASP. In the absence of ASP data, CMS will use the Wholesale Acquisition Cost (WAC). If the WAC is also unavailable, CMS will set the payment at 95% of the AWP. This policy will apply to three new drugs and biologicals in CY 2005: J0135; J1457 and J7674. In addition, CMS has identified nine drugs and biologicals that do not meet the definition for specified covered outpatient drugs and for which CY 2003 claims data is not available. CMS will pay for these drugs using the same methodology.

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.

ORPHAN DRUGS (*Federal Register* page 65807)

“Orphan” drugs are expensive drugs that, by definition, are rarely used. CMS has recognized that packaging these drugs would result in insufficient payment to cover their cost and, therefore, makes separate APC payments for these drugs. CMS designated 12 orphan drugs in CY 2004 and set the rates at 88% of the AWP for ten of them and at 94% of the AWP for the other two.

The final CY 2005 rule continues separate payment for the 12 orphan drugs and has identified two additional orphan drugs for CY 2005 (HCPCS codes J9010 and C9218). CMS will pay for orphan drugs at the higher of 88% of the AWP or 106% of the ASP. CMS has decided not to cap payment at 95% of the AWP, at this time, based on comments received from the proposed rule, but will monitor their decision with respect to future updates. CMS does indicate in this final rule that they will consider using a utilization threshold for future revisions to the orphan drug list.

VACCINES (*Federal Register* page 65807)

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

PAYMENT FOR BLOOD AND BLOOD PRODUCTS (*Federal Register* page 65815)

CMS pays for blood and blood products under the OPPTS through separate APC payments rather than packaging these products into the APCs for the procedures with which they were administered. Generally, CMS prefers to use Medicare claims data when setting payment rates, but has had problems establishing rates for blood and blood products. Since the implementation of the OPPTS, payment rates for blood and blood products have been based on external data due to limited Medicare claims data. CY 2000 rates were based on external data, which were then trended forward to 2001 and 2002. These rates were reduced, subject to limits, in CY 2003 and payments were frozen at the CY 2003 level in CY 2004.

For CY 2005, CMS will continue to pay separately for blood and blood products and has established new APCs that place each blood product in a separate APC. CMS determined that several of the blood product APCs contained multiple blood products with no clinical homogeneity and/or whose product-specific median costs may not have been similar. Therefore, CMS is reassigning some of the HCPCS codes already contained in certain APCs to new APCs.

CMS conducted an analysis to look at the billing of blood and blood products as well as reporting of costs and charges in cost centers specific to blood on hospitals’ cost reports. 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. Simulated CCRs were used in cases where CMS experienced problems with the reported claims data. CMS noticed that, in applying this new methodology, the simulated median costs for procedures relying on a low volume of blood units (less than 1,000 per year) showed large decreases compared to CY 2004. For these low-volume blood products, the CY 2005 payment rate will be adjusted to reflect a 50/50 blend of CY 2004 product-specific median costs and the CY 2005 simulated median. Overall, payment rates for blood and blood products increase under this methodology.

PAYMENT FOR OTHER DRUGS (*Federal Register* page 65800)

The law does not specify a payment methodology for separately payable drugs and biologicals that have never been eligible for pass-through status and are not addressed in the categories described above. Drugs of this type include: those that have been paid separately since the implementation of OPSS, but are not eligible for pass-through status; and those that have historically been packaged but, based on CY 2003 claims data, their median cost per day is now above the \$50 packaging threshold. CMS will 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 65714)

In 2002, CMS created new technology APCs as a means to pay for new services and devices that were not represented in the 1996 base year data and did not meet the transitional payment pass-through criteria. A new procedure is assigned to a new technology APC until such time as enough data are collected to allow assignment to a clinically appropriate APC. In CY 2004, CMS established payment levels for these new technology APCs in \$50, \$100, and \$500 intervals. For CY 2005, CMS has identified 24 procedures that had been assigned to new technology APCs and now have adequate data to support assignment into specific clinical APCs. These reassignments will cause a decrease in APC payments for 17 of the 24 procedures, although some of these decreases have been mitigated after revisions that came about based on comments on the proposed rule.

In two instances, CMS has adopted APC rates that reflect a 50/50 blend of the 2003 median cost and the new technology APC payment rate, rather than a pure transition to cost-based rates, due to concerns regarding patient access. Positron Emission Tomography (PET) scans, currently classified into New Technology APC 1516, have been reassigned to New Technology APC 1513 with a blended rate of \$1,150; Intermediate and Complex Proton Beam Therapies (APC 1511) have been reassigned to New Technology APC 1510, with a blended rate of \$850.

PAYMENT FOR DRUG ADMINISTRATION AND CHEMOTHERAPY (*Federal Register* page 65811)

The following HCPCS codes are currently used for the payment of administration of cancer chemotherapy and infusions of other drugs:

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

In CY 2004, CMS proposed to change the coding and payment of these services in order to pay more accurately for the wide range of services and drugs that are packaged into these per visit codes. The proposal was not implemented at that time, but CMS stated that it would reconsider it for CY 2005. The CY 2005 final rule replaces the HCPCS Q codes with CPT codes for drug administration, but crosswalks these CPT codes to the APCs that reflect how the services would have been paid under the old Q codes.

Please note: it is very important that hospitals bill all charges for the packaged CPT codes for drug administration in CY 2005, even though there is no separate payment for them in CY 2005. Remember, CY 2005 claims data will be the basis for CY 2007 OPSS payments.

DEVICE-DEPENDENT APCs (*Federal Register* page 65749)

Device-dependent APCs, as defined by CMS, are APCs that 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 formerly paid as pass-throughs, but are now packaged with the procedure APC.

CMS has consistently experienced problems in determining payment rates for procedures that include devices. For the past three years, when using claims data to calculate APC rates for these procedures, the resulting rates were often substantially less than the cost of the device alone. In CYs 2003 and 2004, CMS determined that many hospitals were not consistently reporting charges for the devices. Therefore, CMS limited the APC median cost calculation to claims that reported a separate charge for the device, while placing limits on rate decreases for these APCs. Because CMS eliminated the HCPCS codes for devices in 2003, it is impossible to follow past practice and limit the calculation to claims with device charges. Therefore, CMS has determined rates for device-dependent APCs to be **the greater of**: median costs calculated using CY 2003 claims data or 95% of the APC payment median for CY 2004 (as opposed to 90% under the proposed rule).

Out of 42 device-dependent APCs for CY 2005, rates for 21 decreased by 2.3% and 3 decreased by a lesser amount. **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 is requiring hospitals to bill all device-dependent procedures using the appropriate C-codes for the included devices. The goal is to use all single bills for device-dependent APCs for CY 2007 OPPS rates, which will be based on CY 2005 claims.**

OBSERVATION SERVICES (*Federal Register* page 65828)

In CY 2002, CMS established a separate OPPS payment APC for observation services for three medical conditions: chest pain; congestive heart failure and asthma. A number of accompanying requirements were established, including the provision of specific diagnostic tests to beneficiaries based on their diagnoses. CMS has responded to 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, beginning in CY 2005, **the following tests will 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; or
- for chest pain, two sets of cardiac enzyme tests; either two creatine phosphokinase (CPK) or two troponins and two sequential electrocardiograms.

CMS has also revised its requirements for counting patient time in observation care such that time in observation care ends when the outpatient is actually discharged from the hospital or admitted as an inpatient.

The final rule lists the following requirements in order 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 and **the hospital must provide an appropriate ICD-9-CM admission or principal diagnosis code on its bill in order to receive payment.** In order to give hospitals time to

incorporate this requirement into their billing systems, it does not become effective until April 1, 2005.

- 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 eight 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 65834)

The inpatient list specifies those services that will only be paid for by CMS in an inpatient setting. These procedures are assigned a status code of “C” and hospitals are advised to admit beneficiaries requiring these procedures in order to receive payment. CMS has identified 22 procedure codes for removal from the inpatient list, but rejected an APC Panel recommendation to eliminate completely the list of inpatient only procedures.

PAYMENT FOR BRACHYTHERAPY SOURCES (*Federal Register* page 65838)

The MMA requires that 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. 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.

In order to accomplish this MMA requirement, CMS previously revised the status codes for brachytherapy sources to “H” and has revised the definition of status code H to include “non-pass-through brachytherapy sources paid on a cost basis.” Beneficiaries are not subject to a co-pay for these services. In addition, CMS has added three new brachytherapy HCPCS codes for CY 2005. Hence, three new code H pass-through devices appear in CY 2005.

NEW PROCEDURE CODES TO REFLECT OPPTS CHANGES RELATING TO THE COVERAGE OF INITIAL PREVENTATIVE PHYSICAL EXAMINATIONS (*Federal Register* page 65726)

The MMA mandates that Medicare Part B cover an initial preventative physical examination for new beneficiaries. The provision applies only to beneficiaries with coverage beginning on or after January 1, 2005 and only covers an initial preventative physical exam that is performed within the first six months of coverage. CMS has amended its regulations to allow for payment of these exams in the hospital outpatient setting. CMS has established a new HCPCS code for the initial exam (G0344 with status indicator V) and three new codes for the EKG that is a required component of the exam (G0366 with

status indicator B, G0367 with status indicator S and G0368 with status indicator A). The three EKG codes reflect the various scenarios under which a beneficiary may present for the service. Only two of these new codes are payable under OPSS and a hospital must bill for both in order to receive payment. Code G0367 is assigned to APC 0099 and code G0344 is assigned to APC 0601. Together, these APCs pay \$78.

PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES (*Federal Register* page 65729)

The MMA required that screening and diagnostic mammography be excluded from payment under OPSS, to be paid under the Physician Fee Schedule. This CY 2005 final rule reflects this provision of the MMA, which results in slightly higher payment rates for these services.

PAYMENT FOR ANCILLARY OUTPATIENT SERVICES WHEN THE PATIENT EXPIRES (*Federal Register* page 65841)

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.” In CY 2004, CMS created APC 0375 to pay for services provided on the same date billed for a procedure with modifier code CA. 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 has used the standard APC methodology to determine a rate of \$3,214.22 for APC 0375 (compared to \$2757.68 in the proposed rule).

ASSIGNMENT OF “UNLISTED” HCPCS CODES (*Federal Register* page 65724)

“Unlisted” HCPCS 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. For CY 2005, CMS has reassigned 22 unlisted HCPCS codes to lower level APCs.

V. GUIDELINES FOR EVALUATION AND MANAGEMENT CODES (*Federal Register* page 65837)

Emergency and clinic visits are paid based on three levels of service: low, mid, and high. The level is determined by the reported evaluation and management (E/M) CPT code. There is currently no uniform policy to determine 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. CMS is continuing to work on a proposal and has not yet made plans for implementation of uniform coding guidelines. CMS anticipates providing at least six to 12 months notice to allow for training and system changes.

VI. PARTIAL HOSPITALIZATION (*Federal Register* page 65847)

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). OPSS providers are paid on a per diem basis for partial hospitalization services. In this final rule, CMS reduced the PHP APC per diem amount to \$281.33 (from \$286.82 in CY 2004 and \$292.19 in the proposed rule), of which \$56.33 is

the beneficiary's coinsurance. CMS establishes a separate outlier threshold for PHP payments to CMHCs at 3.5 percent times the APC payment amount. Payment to CMHCs for outliers will be made at 50% of the costs in excess of the threshold.