

Medicare Outpatient PPS: The Final Rule for CY 2003

Background

On November 1, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a final rule containing calendar year (CY) 2003 changes to the hospital outpatient prospective payment system (OPPS).

The rule makes significant changes to Ambulatory Payment Classifications (APC) weights and rates, amends important policies related to new technology and outlier payments, finalizes the criteria that will be used to create new categories of medical devices eligible for transitional pass-through payments, and allows CMS to suspend Medicare payments "in whole or in part" if hospitals fail to file a timely and acceptable cost report.

The final rule takes effect January 1, 2003.

PPS Rate Update

Under current law, the 2003 outpatient PPS update is to equal the full hospital inpatient market basket percent increase, or 3.5 percent. The average per case increase, however, will be 3.7 percent. As explained further below, CMS has projected that spending for new technology pass-through payments will equal only 2.3 percent of total outpatient PPS payments, rather than the full 2.5 percent allowable by law. As a result, the 0.2 percent difference has been returned to the conversion factor, thus funding the base APC rates. The net effect of this and other provisions in the 2003 rule is an estimated 3.1 percent increase in per case payments for urban hospitals, and a 6.2 percent increase in per case payments for rural hospitals.

The 2003 outpatient conversion factor for APC payments, after accounting for budget neutrality adjustments, is 52.15, up from 50.90 in 2002.

Calculation of the CY 2003 Rates and Weights

The final rule takes a number of steps to correct the erroneous payment rates of 2002. These errors, as CMS stipulates, were mainly the result of its complicated attempt to "fold-in" 75 percent of the costs associated with new technology pass-through payments into the base APCs. The agency has acknowledged that this policy resulted in 2002 payments that were too high for services using new technologies and too low for more basic services, such as clinic and emergency room visits.

Therefore, payments for several APCs will experience a significant swing from 2002 to 2003. While payments for procedures using new technology drugs and devices will decline (although this decline will not be as severe as payment reductions proposed in the August 9 NRPM), payments for most other services will experience an increase.

The data and methodology used to set the 2003 rates is quite different from that used in 2002.

- The 2003 APC payment weights and rates will be calculated using actual hospital claims data from **April 1, 2001 through March 31, 2002**. The calendar year (CY) period was used to set payment rates in the NPRM. CMS has indicated that it has chosen to use this time period because:
 - ✓ It represents the most recent charge data available.
 - ✓ The claims from this entire period reflect 2001 rates, due to the delay in implementation of the 2002 rates until April 1, 2002.
 - ✓ It provides the most reliable charge data for services that use medical devices, because device category codes were in effect for the entire time period. Beginning April 1, 2001, eligibility for pass-through payment switched to categories of devices rather than on an item-specific basis.
- The number of claims used to set the APC payment rates has increased from less than 40 million in 2002 to more than 60 million in 2003. CMS has included multiple procedure claims (those where multiple services are delivered during the same visit or operative session) in cases where each line item contains a separately payable service. CMS has excluded, however, claims containing procedures that could not be performed without a device, yet where a device was not separately identifiable on the bill, thus creating a more valid set of “clean claims” for use in calculating payments for APCs using devices.
- The majority of new technology drugs and devices are no longer eligible for transitional pass-through payments. The costs of these drugs and devices have been incorporated into the APC payment rates and weights. A more detailed explanation of changes to transitional pass-through payments is below.
- CMS has implemented a special “**buffering rule**” to mitigate substantial decreases in APC payments for 2003. Under this policy, any APC that would have declined by more than 15 percent will now have its rate altered to one-half the difference between its scheduled decline (from hospital claims data) and negative 15 percent. For example, if hospital claims data indicated that APC 000 was to decline by 25 percent from 2002 to 2003, CMS will limit the decline to 20% (or half the difference between 25 percent and 15 percent).

The funding for this policy was done in a budget neutral manner, resulting in payments being taken from all other APCs (those that did not experience declines greater than 15 percent) to prevent the deep losses for specific APCs. The rule does not identify this amount, although CMS has **told us** that it was close to 5 percent.

Finally, several outpatient services have received special treatment:

- ***Procedures with Device Cost of 80 Percent or More.*** For APCs with device costs representing 80 percent or more of the overall APC payment, the agency has supplemented hospital claims data with external data provided by manufacturers. CMS gave a weight of three to the median acquisition cost of the device as provided by external data, and a weight of one to the medical cost provided by hospital claims data. This new 3:1 ratio was then used to calculate the total cost of the procedure. The buffering rule was applied, if necessary, to adjust its total cost. This methodology was used for: APCs 107, Insertion of Cardioverter-Defibrillator; 108, Insertion/

Replacement/Repair of Cardioverter-Defibrillator Leads; 222, Implantation of Neurological Devices; and 259, Level VI ENT Procedures.

- **Blood.** CMS was greatly concerned about the significant payment reductions in blood and blood products even after the buffering rule was applied. The agency determined that these products should be further protected from payment decreases, and hence limited to no more than 15 percent reductions in payment from 2002 to 2003 for the 27 blood APCs. The agency will clarify billing and coding for blood-related services in an upcoming Program Transmittal.
- **Orphan Drugs.** CMS will pay for the following three orphan drugs on a reasonable cost basis, rather than package the cost of these drugs into outpatient APCs: J0205 Alglucerase injection; J0256 Alpha 1 proteinase inhibitor; and J09300 Gemtuzumab ozogamicin.
- **Vaccines.** Similar to orphan drugs, the agency will pay for influenza and pneumococcal pneumonia vaccines under a reasonable cost methodology.
- **Drug-Eluting Stents.** CMS has adopted as final its proposal to create two new codes (G0290 and G0291), which will be activated on April 1, 2003 if such stents are approved by the Food and Drug Administration (FDA), to pay for drug-eluting stent technology. The codes will receive payment under APC 0656, Transcatheter Placement of Drug-Eluting Coronary Stents.

A spreadsheet comparing the changes in APC payment rates and weights from CY 2001 to CY 2003 is available on WHA's website. Go to <http://www.wha.org/mo/wha/govtpmt/index.htm>

Transitional Pass-through Payments

In 1999, Congress created temporary additional payments, or "transitional pass-through payments," for certain innovative medical devices, drugs and biologicals to ensure that Medicare beneficiaries had access to new technology. These pass-through payments were capped at 2.5 percent of total OPPS payments, and 2.0 percent beginning in 2004. To fund these payments, CMS reduced payments for all other outpatient services. By law, pass-through payments were to last for at least two, but not more than three years.

CMS has estimated pass-through payments for 2003 at \$427 million. By law, the agency may allocate up to 2.5 percent of total outpatient PPS payment for these new technologies, or \$467 million. Because CMS' estimate represents only 2.3 percent of total program payments, **a pro-rata reduction will not be necessary in 2003.** Additionally, CMS will only reduce the conversion factor by 2.3 percent (rather than 2.5 percent) and will return 0.2 percent of payments back to the base APCs.

Payment for Medical Devices

The final rule adopts CMS' proposal to retire 95 of the 100 categories of devices previously approved for new technology pass-through payments, effective January 1, 2003. The rule also adopts as final its proposal to package the costs of medical devices no longer eligible for pass-through payments into the costs of the procedures utilizing these devices. Medicare payment for APCs that use devices will be based on a relative weight calculated in the same manner as relative weights for all APCs.

Hospitals will no longer bill a “C” code for these devices. Rather, hospitals will submit charges for devices in the supply, implant or device revenue center that most appropriately describes the implant. The expiring pass-through drug and device codes will be deleted, and the line item use of the codes will be rejected. CMS will not allow its typical 90-day grace period for the codes scheduled for deletion. If CMS were to permit a grace period, then it would have needed to project additional costs in the pass-through payment pool, potentially triggering a pro-rata reduction.

Five categories of pass-through devices and two new categories of devices will receive pass-through payments in 2003. Payment for these items will be calculated based on hospital charges, converted to costs according to a hospital-specific cost-to-charge ratio, less that portion of the APC rate already associated with the device.

Creation of New Device Categories

The Medicare, Medicaid, and SCHIP Beneficiary Improvement and Protection Act of 2000 (BIPA) required the use of categories to determine the eligibility of devices (but not drugs or biologicals) for transitional pass-through payments beginning April 1, 2001. While the statute set broad criteria for establishing initial categories, it required CMS to develop criteria for establishing new categories of devices. On November 2, 2001, CMS released an interim final rule with a comment period that set forth the criteria it would use in establishing new categories of devices.

In the November 9 final rule, CMS announced that it would maintain the criteria set forth in the 2001 rule for establishing new categories of devices. First, devices must offer “substantial clinical improvement” in medical benefits, as compared to the benefits obtained by devices in previously established categories or other available treatments. Second, the estimated device cost to hospitals in a new category must be “not insignificant” relative to the payment rate for the applicable procedure. A device cost is “not insignificant” if it meets the following criteria:

- The estimated reasonable cost of the device exceeds 25 percent of the applicable APC payment for the service associated with the category of devices.
- The estimated reasonable cost of the device exceeds the device-related portion of the APC payment amount for the service associated with the category of devices by at least 25 percent.
- The estimated total cost of the devices in the category, less the portion of the APC payment allocated to the devices, exceeds 10 percent of the total payment for the associated APC.

In addition, CMS has clarified that a device must be approved or cleared by the FDA before it would develop a category for payment.

WHA is pleased that the agency has adopted as final the above narrow criteria, as it will help focus pass-through payments on those devices that offer enhanced benefit to beneficiaries and which would truly represent a substantial financial loss to hospitals.

Payment for Drugs and Biologicals

Similar to devices, and as proposed in the NRPM, CMS will remove from the pass-through list those drugs that have received pass-through payments for at least two years as of January 1, 2003. Low-cost drugs (those less than \$150) will be packaged into their corresponding APCs. High-cost drugs (those more than \$150) will receive separate APC payment. The agency states that it would prefer to package the costs of all drugs into the procedures with which they are associated, a policy supported by WHA, and that it will continue to study various payment options for high-cost drugs in 2004.

Seventeen drugs/biologicals will remain on the pass-through list in 2003. Payments for these items will be calculated based on the July 2002 Redbook prices for Average Wholesale Price (AWP). In general, payment is set at 95 percent of AWP, less that portion of the APC that is already associated with the drug. This portion is subtracted from the base payment (or 95 percent of AWP), and is calculated using a ratio of acquisition cost to AWP:

- For sole-source drugs, the ratio is 0.71 (up from 0.68)
- For multisource drugs, the ratio is 0.68 (up from 0.61)
- For generic drugs, the ratio is 0.46 (up from 0.43)

There are two exceptions to this payment rule: If the drug is new and no cost is already included in an associated APC, then the pass-through payment amount will be the full 95 percent of AWP. Second, if the drug is new but it is a substitute for a drug that currently receives payment through an unpackaged APC, then the pass-through payment amount will be the difference between 95 percent of AWP and the payment rate for a comparable dose of the associated drug's APC.

Payment for Brachytherapy

The agency has finalized its proposal to discontinue pass-through payments for devices of brachytherapy (i.e., brachytherapy seeds, needles, and catheters) beginning January 1, 2003. The costs of all devices for two types of brachytherapy – remote afterloading high intensity brachytherapy and prostate brachytherapy – will be packaged into the APC. Brachytherapy seeds (a mechanism used to deliver brachytherapy to patients) for all other services will continue to be paid separately in 2003. As with other pass-through devices, there will not be a grace period for billing these category codes.

Outlier Payment

Outlier payments are additional payments made to the APC amount to help mitigate some of the expense of high-cost cases. As supported by WHA, CMS will adopt its proposal to increase the outlier pool to 2.0 percent of total OPPS payments, up from 1.5 percent in 2002. CMS will also lower the eligibility threshold for outliers to 2.75 times the APC payment rate, from 3.5 times, thus making it easier for hospitals to qualify for these payments. Due to revised simulations on the new claims data and methodologies described above, the agency determined that it must lower the outlier payment percentage to 45 percent, from 50 percent in 2002, in order to fund outlier payments at 2.0 percent.

Evaluation and Management (E/M) Services

Since the implementation of the OPPS, hospitals have coded clinic and emergency department (ED) visits using the same current procedural terminology (CPT) code as physicians. CMS has recognized that existing E/M codes correspond to different levels of physician effort but do not adequately describe non-physician resources. CMS has thus allowed each hospital to develop its own set of guidelines to map the five levels of effort represented by the CPT codes to the three levels of effort represented by hospital APCs. The only guidelines hospitals were required to follow were that the services be documented and medically necessary, and that the mapping reasonably reflects the intensity of the hospital's resources.

Although hospitals were anticipating that CMS would propose a national, uniform E/M coding system in 2003, the agency chose not to do so. The agency has agreed that the most appropriate forum for developing E/M code definitions and guidelines is an independent expert panel. CMS identified the AHA and the American Health Information Management Association (AHIMA) as key players in this process. The AHA and AHIMA have agreed to accept CMS' recommendation and convene a group of

professional organizations representing physicians, nurses, hospitals and health information managers, as well as coders that have real-world experience developing and implementing hospital E/M coding. This panel will strive to develop a consensus recommendation for CMS by next spring.

CMS has determined that each hospital may retain its current coding system for clinic and ED visits, rather than implement the new “G” codes it presented in the proposed rule, until national coding guidelines with standard definitions are established. The agency will not finalize its proposal delineating what constitutes level-one emergency and clinic visits. Hospitals, however, should review and refine their existing E/M mapping system to make sure it complies with CMS’ recent recommendations that separately reportable and payable services are excluded when determining appropriate levels of hospital resource consumption.

Observation Services

CMS adopted as final provision to provide separate payment for patients who are directly admitted from a physician’s office into observation care with chest pain, congestive heart failure (CHF) or asthma. We are disappointed, however, that CMS adopted its proposed coding and payment methodology, which we viewed as complicated and overly burdensome. CMS will implement two new G codes to track direct admissions for observation services: G0263, Direct admission of patient with diagnosis of congestive heart failure, chest pain or asthma for observation; and G0264, Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain or asthma. Code G0263 will be assigned to APC 0339, Observation Services, and G0264 will be assigned to APC 600, Low Level Clinic Visit (a change from the proposed rule, which assigned this code to APC 0706, New Technology – Level 1). CMS acknowledges that this new coding system is burdensome, and indicated that it will explore alternative coding options in the future.

Inpatient-only Procedures

We are also disappointed that CMS will continue to use an inpatient-only procedure list, which identifies services that are unable to receive payment if they are performed in an outpatient setting. WHA continues to believe this list should be eliminated, as physicians, not hospitals, determine what procedures should be performed, as well as whether a patient’s condition warrants an inpatient admission.

In addition, CMS is adopting as final the requirement that if a procedure on the inpatient list is performed to resuscitate or stabilize an outpatient with an emergency, life-threatening condition, and the patient dies before being admitted as an inpatient, then the hospital should submit an outpatient claim for all services furnished. This claim should include the inpatient-only procedure (identified by status indicator C) and a new modifier, which CMS indicated would be announced by Program Memorandum. Claims with a procedure code on the inpatient list that are billed with the new modifier will be paid under APC 977, New Technology – Level VIII.

Interim APC Assignments for New Codes

In the final rule, CMS added a handful of new HCPCS codes and assigned them to existing APCs. Because the assignment of these codes was not subject to public comment in the proposed rule, CMS will accept comments if they are received by December 31. The new codes are identified in Addendum B with an indicator of NI.

Beneficiary Coinsurance and Deductible

By statute, the 2003 national unadjusted beneficiary coinsurance for an APC may be no more than 55 percent of the APC payment rate. This is the same percentage as in 2002. The 2003 hospital inpatient

deductible is \$840, up from \$812 in 2002.

Payment Suspension for Unfiled Cost Reports

The rule adopts as final its proposal to allow the Secretary more flexibility in payment suspensions. Beginning in 2003, if a provider fails to file an acceptable cost report in a timely manner, the Secretary may choose to suspend certain payments, rather than all payments. This increased flexibility will allow hospitals to receive partial payment from Medicare, and thus lessens the financial impact of payment suspensions on providers.