Regulatory Advisory

AHA
Advancing Health in America

AHA's Regulatory Advisory, a service to AHA members, will be produced whenever there is a significant regulatory development that affects the job you do in your community.

Medicare Outpatient PPS: The Proposed Rule for CY 2004

A Message to AHA Members:

On August 12, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule with changes to the calendar year 2004 outpatient prospective payment system (OPPS). This proposed rule includes statutory changes for 2004 as well as considerable policy changes, such as revisions to the Ambulatory Payment Classifications (APC) weights and rates; payments for drugs, devices and biologicals; and payments for outliers. A final rule expected around November 1 will take effect January 1, 2004.

Go to www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/register/arfedregister.html to view the proposed rule.

As mandated by law, the rule proposes to increase outpatient hospital payments by 3.5 percent – the estimated full change in the hospital market basket for 2004. This update, however, excludes changes in hospital payments for outliers and pass-through drugs and devices, as well as hold harmless and transitional corridor payments. **The AHA is concerned the impact of the expiration of hold harmless and transitional corridor payments at the end of 2003 will be greater than the update to hospitals – resulting in an actual decline in Medicare outpatient revenue in 2004 as compared to 2003.**

By law, pass-through payments for new technologies will decline from a cap of 2.5 percent of total OPPS payments to 2.0 percent in 2004 and beyond. Pass-through payments must be funded in a budget neutral manner, and thus CMS is proposing to reduce all other outpatient services by 2.0 percent. At this time, CMS has not proposed a pro-rata reduction for 2004, saying it is uncertain whether estimated pass-through spending in 2004 would exceed the 2.0 percent pool available. **The AHA is concerned, however, that the carve out from base OPPS rates may be greater than the funds spent on pass-though payments for new technologies.**

While the rule does not propose a new evaluation and management (E/M) coding system for billing emergency department and clinic visits, it does review the recommendations from an expert panel co-chaired by the AHA and the American Health Information Management Association (AHIMA). **We believe that these E/M coding recommendations will meet hospitals' needs. And, while we support CMS' proposal to give providers the time**

necessary to implement new provisions, we are concerned that continued use of current codes after October 16, 2003 may be in conflict with the Health Insurance Portability and Accountability Act. The AHA will urge CMS to issue guidance to address this potential problem.

After reviewing this advisory, check off the following items from your to-do list:

- ✓ Share this advisory with your senior management team.

- ✓ Model the impact of the proposed APC changes on your 2004 Medicare revenue. A spreadsheet comparing the changes in APC payment rates and weights from CY 2001–2004 is available for AHA members at www.hospitalconnect.com/aha/key_issues/opps/resources/toolsresources.html. Please note that you must first login to view the spreadsheet.

- ✓ Urge your lawmakers to extend the rural hold harmless and transitional corridor payment protections to hospitals for three years.

- ✓ **Submit your comments on the rule to CMS before the October 6th deadline.** Feel free to use the AHA's comment letter as a guide; it will be available at the end of September at www.aha.org.

While the AHA is pleased with many aspects of the rule, the outpatient PPS continues to be severely underfunded, paying hospitals about 86 cents for every dollar providing outpatient care to Medicare beneficiaries. Together, we must convince CMS and Congress that inadequate payment rates and updates must be addressed to ensure continued access to outpatient services for Medicare beneficiaries.

Sincerely,

Rick Pollack
Executive Vice President

September 12, 2003

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Background

On August 12, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule with changes to the calendar year 2004 outpatient prospective payment system (OPPS). This proposed rule includes statutory changes for 2004 as well as considerable policy changes, such as revisions to the Ambulatory Payment Classifications (APC) weights and rates; payments for drugs, devices and biologicals; and payments for outliers. A final rule expected around November 1 will take effect January 1, 2004.

Go to www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/register/arfedregister.html to view the proposed rule.

Comments on the proposed changes are due to CMS by **October 6th.** A final rule expected around November 1 will take effect January 1, 2004.

PPS Update to the Conversion Factor

By law, the outpatient PPS rate update for 2004 is equal to the full rate of change in the hospital inpatient market basket – a measure of inflation in goods and services used by acute care hospitals. The hospital market basket increase forecast for fiscal year 2004 is 3.5 percent, as published in the inpatient PPS proposed rule on May 19, 2003.[1]

Also under current law, new technology pass-through payments will decline to a maximum of 2.0 percent of total OPPS payments in 2004 (see below). Last year, CMS set pass-through payments at 2.3 percent of total OPPS payments. The difference of 0.3 percent has been added back to the conversion factor to fund all other APCs.

The proposed conversion factor for 2004, after also accounting for a 1.003 budget neutrality adjustment due to wage index changes, is $54.289 in 2004, up from $52.151 in 2003.[2]

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[1] Note that for the outpatient PPS final rule, CMS will use the actual inpatient hospital market basket increase of 3.4 percent, as published in the inpatient PPS final rule on August 1, 2003.

[2] $52.151 x 1.035 (update) = $53.976 x 1.003 (pass-through) = $54.138 x 1.003 (budget neutrality) = $54.29

Recalibration of the APC Weights

Since the implementation of the OPPS in August 2000, payment rates for specific APCs – the classification system Medicare uses to pay for specific items or services – have fluctuated dramatically. For 2004, the proposed rates are generally more stable, although individual APCs may still be much higher or lower in 2004 as compared to 2003. There are several reasons for changes in payment rates, including:

- **Use of more recent claims data.** The rule proposes to use hospital claims data from April 1, 2002 through December 31, 2002 to calculate the final 2004 payment rates and weights.[3] The agency proposes to not include first quarter claims, as these were used to set the payment rates for 2003.

- **Use of more multiple procedure claims.** The AHA has urged CMS to include more claims data in the calculation of the APC payment rates, especially those that contain charges for more than one service or procedure. The number of multiple procedure claims used will help improve data quality in APC recalibration. CMS is proposing to expand the number of Healthcare Common Procedure Coding System (HCPCS) codes it ignores on a claim – from 3 in 2003 to 60 in 2004 – for the purposes of creating a pseudo single-procedure claim. In addition, the agency is proposing to attribute charges to separately payable HCPCS codes based on the codes' dates of service, which would require hospitals to enter a line item date of service for every OPPS charge.

- **Modification of the 2003 "dampening rule**." The agency is proposing to implement a "dampening rule," similar to that adopted in the 2003 final rule, and limit substantial reductions in specific APC payments.

A spreadsheet comparing the changes in APC payment rates and weights from CY 2001–2004 is available for AHA members at www.hospitalconnect.com/aha/key_issues/opps/resources/toolsresources.html. Please note that you must first login to view the spreadsheet.

Transitional Pass-Through Payments

In 1999, Congress created temporary additional 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 by law at 2.5 percent of total OPPS payments until 2003, and then at 2.0 percent in 2004 and thereafter. **CMS is proposing to set the transitional pass-through payment pool at the full 2.0 percent in 2004, and, because the payments are budget neutral, all other outpatient services will be reduced by 2.0 percent in 2004.**

By law, if estimated pass-through payments exceed the payment cap in the coming year, then CMS must reduce payments for all pass-through items in order to prevent an increase in overall Medicare spending for outpatient services. In the proposed rule, CMS states that it is "uncertain whether estimated pass-through spending in 2004 will exceed $456 million (2.0 percent of total estimated OPPS spending) because it has "not yet completed the estimate of pass-through spending for a number of drugs and devices" (*Federal Register*, p. 47992).

CMS data indicate that 2004 pass-through spending is projected at only $212 million ($153

[3] At the time of publication of the proposed rule, however, CMS only had access to hospital claims data through November 1, 2002. Thus the 2004 proposed rates are based on data from April 1 through November 1.

million for drugs and $59 million for devices) – or half the amount currently allocated. Thus, the AHA believes the payment cap should be lowered to 1.0 percent, with the remaining 1.0 percent returned to the base APC rates so that it may be used fund all other outpatient services. Moreover, CMS set the 2003 payment cap at 2.3% of total OPPS payments but has not provided any data or information on actual pass-through payments in 2003. **The AHA is concerned that CMS may be carving out more funds than what is actually spent on pass-though payments for new technologies. We will push CMS to release more information on use of these payments, and appropriate changes that may be needed.**

Payment for Medical Devices

By law, categories of devices are eligible for pass-through payments for at least two years, but not more than three. CMS proposes that two of the device categories approved for new technology pass-through payments would expire January 1, 2004 because they first received pass-through payment under OPPS in 2000 or 2001. The agency is seeking to package the costs of these pass-through devices into the APCs using the devices. Medicare payment would be based on a relative weight calculated in the same manner that relative weights for all APCs are calculated.

In 2004, eight categories of pass-through devices will continue to receive pass-through payments. These payments would 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. For the last two years, CMS has deducted from the pass-through payments an "offset" amount, or the estimated cost of devices already packaged into the APC groups. In some cases, however, the APCs may not contain any identifiable costs associated with the device. Thus, for 2004, the agency proposes to modify its policy so that an offset would be applied only to a new device category when CMS can determine that an APC contains costs associated with the device. The agency also proposes to set the offset in 2004 to $0, since the remaining device categories are not replacing any devices whose costs have been packaged into the APCs, and new device categories have been proposed.

The agency is requesting comment regarding the handling of device offsets in 2005 given that – at the direction of CMS in its 2003 final rule – hospitals are not reporting device "C" codes on 2003 hospital claims. Last year hospitals were told not to bill C codes for devices removed from the pass-through payment list, but rather submit charges for devices in the supply, implant or device revenue center that most appropriately describes the implant. This year, the agency states that it needs this information to ensure accurate rate setting in the future. Now, CMS is considering two options – one, reinstating C codes for expired device categories, and allowing continued identification of devices and costs on a claim, or two, using charges from claim lines under certain revenue codes as proxies for the device charges that would have been billed. The agency is soliciting comment on whether or not it should require device coding, and if so, the preferable option.

Payment for Drugs, Biologicals, Radiopharmaceutical Agents and Blood

Currently, Medicare pays for drugs, biologicals, radiopharmaceuticals and blood in one of three ways: a transitional pass-through payment, a packaged payment or a separate APC payment.

Transitional Pass-Through Payments. The proposed rule would remove eight drugs from the new technology pass-through payment list effective January 1, 2004, while 14 drugs would remain on the list. Payments for drugs on the pass-through list are set at 95 percent of the drug's average wholesale price (AWP), less the portion of the APC payment already associated with the drug. Traditionally, CMS has used the AWP published in the Red Book. For 2004 and beyond, the agency proposes using the AWP listed in the most recent quarterly update of the Single Drug Pricer (SDP). Because the January SDP will not be available in time for the OPPS final rule, CMS also proposes to wait until January 1, 2004 to announce new prices for pass-through drugs through program memoranda and updates to the CMS' PRICER software. Moreover, CMS would update the AWP for pass-through drugs on a quarterly basis. The AHA is concerned that this policy would negatively impact pass-through spending projections (as spending would not be determined until after release of the final rule) and that hospital information systems would not be programmed prior to the January 1, 2004 start date of the OPPS rule.

Packaged APC Versus Separate APC Payment. In 2002, CMS adopted the policy that low-cost drugs (those less than $150) would be packaged into their corresponding APCs, but high-cost drugs (those more than $150) would receive separate APC payment. The proposed rule would continue this policy, although with minor modifications**.** First, the proposed rule would change the calculation of this threshold amount from a median cost of $150 *per line* to a median cost of $150 *per day*. Second, given this slightly different methodology and newer data, and the number of drugs that would move from separate payment to packaged payment (and vice versa), CMS proposes providing exception to the packaging rule for 2004. Specifically:

- Currently packaged drugs with costs above $150 would receive separate payment.
- Currently separately payable drugs with costs below $150 would continue to receive separate payment.
- Drugs whose pass-through status expires and whose costs are below $150 would receive separate payment.
- Drugs and radiopharmaceuticals with costs below $150 per day would be packaged into procedures with which they are billed.

Dampening Rule. For separately paid drugs and radiopharmaceuticals (but not devices) with payments that decline by more than 15 percent from 2003 to 2004, CMS proposes implementing a "dampening rule" to mitigate hospital losses for these services. Under this policy, drug and radiopharmaceutical APCs with payments that decline by more than 15 percent would have its rate reduction limited to one-fourth (versus one-half in 2003) of the difference between its scheduled decline, based on hospital claims data, and negative 15 percent. For example, if hospital claims data indicated that APC 000 was to decline by 35 percent from 2003 to 2004, CMS has proposed to limit the decline to 20% (or 15% plus one-fourth of the difference between 35 percent and 15 percent). Funding for this policy would be budget neutral and payments would decline slightly for all other APCs to prevent deep losses for specific APCs. The rule does not specify this budget neutrality adjustment, or the impact of different reduction rates – such as one-fourth versus one-half. Last year, CMS indicated verbally that payments for all other APCs declined by close to 5 percent in order to ensure certain APCs did not undergo significant losses.

Drug Administration. Currently Medicare pays separately for the administration of drugs through one of four "Q" codes. CMS is concerned, however, that costs appear to vary widely based on whether the drug is packaged or in a separately payable APC. Additionally, each code is reported once per visit no matter how many drugs are administered. The proposed rule examines four options for drug administration payment and solicits comment on each:

1. To continue the current coding structure and payment policy.
2. To eliminate the four existing code and create eight new codes to differentiate administration of packaged versus separately payable drugs.
3. To eliminate the four existing code and create six new codes to differentiate administration of packaged versus separately payable drugs.
4. To continue using of the current codes but create new payment policy by modifying the outpatient code editor (OCE) to allow it to pay differently for the administration of packaged versus separately payable drugs.

The AHA is concerned that implementation of options two through four would be extremely difficult, overly complicated, expensive and burdensome.

Generic Drugs. The agency proposes using 43 percent of AWP, rather than hospital claims data, to pay for drugs, biologicals or radiopharmaceuticals if the Food and Drug Administration approved a generic alternative between October 2001 and December 2002. This policy would effect six drugs for 2004.

Orphan Drugs. Last year, four orphan drugs – drugs used solely for the treatment of rare disorders where no other treatment is available – were excluded from payment under OPPS and paid based on reasonable cost. This year, seven additional drugs have been identified as orphan drugs. Given that more drugs likely will qualify in the future, CMS proposes to no longer pay orphan drugs at cost, but rather create a new, separately payable APC for each orphan drug. Payment would be based on the same methodology used to pay for all other APCs. The AHA is concerned that reimbursement may not be adequate under OPPS, thus impairing the access of beneficiaries to these rare, but necessary, drugs.

Vaccines. In the rule, CMS proposes to continue payment for influenza and pneumoccal pneumonia vaccines under a reasonable cost methodology for 2004.

Blood and Blood Products. CMS proposes to continue separate payment for blood and blood products, and continue a special dampening rule that would limit any decrease in APC payment from 2003 to 2004 to approximately 10 percent.

Intravenous Immune Globulin. Although the agency received requests to reclassify intravenous immune globulin as a blood product, CMS proposes to continue its classification as a biologic.

Procrit and Aranesp. CMS proposes to continue its current payment policy for Procrit and Aranesp, including use of the current conversion ratio.

Drug Coding. Similar to device coding, packaging drugs into APCs will result in a lack of drug related data to set payment rates in the future. For example, beginning in 2005,

CMS will not have data on the costs of drugs packaged into APCs, and will not be able to determine whether drugs should be removed from packaged status for separate payment. CMS proposes requiring the separate coding of all individual drugs used to treat a patient, even if payment for those drugs are packaged into an APC.

New Technology APCs

The rule proposes a comprehensive restructuring of new technology APCs, which are used to pay for new or rarely performed procedures for which CMS lacks sufficient cost data to make an assignment to a clinical APC. These APCs are defined on a cost basis, not the clinical characteristics of a service. The payment rate for each new technology APC is based on the midpoint of a range of costs.

The agency proposes to establish narrower cost bands so that payments more accurately target the expected cost of the procedure. Specifically, the rule would create cost bands from $0 to $100 in increments of $50, from $100 through $2,000, in increments of $100, and from $200 through $6,000 in increments of $500. CMS would continue to retain two parallel sets of new technology APCs, one with a status indicator "S" and the other with a status indicator of "T" to indicate when the multiple procedure reduction policy does and does not apply. The result is approximately 75 total new technology APCs.

Additionally, CMS proposes to delete four HCPCS codes that are currently paid in new technology APCs (C1088 – laser optic treatment system, C9701 – stretta system, C9703 – bard endoscopic suturing system, and C9711 – H.E.L.P. apheresis system) because they represent equipment used to *provide* a service, rather than an entirely new service.

Outlier Payments

Outlier payments are additional payments to the APC amount to mitigate some of hospitals' losses when treating unusually high-cost cases. The rule proposes to maintain the outlier pool at 2.0 percent of total OPPS payments (the same level as in 2003).

For 2004, CMS would establish two separate outlier thresholds, one for hospitals and one for community mental health centers (CMHCs). Hospitals would continue to have a qualifying threshold of 2.75 times the APC payment amount. CMHCs, which receive payment for partial hospitalization programs service, would have a qualifying threshold of 11.75 times the APC payment amount. This higher threshold is due to an excessive amount of outlier payments being made to CMHCs. Because CMHCs are projected to receive 0.36 percent of total OPPS payments in 2004, excluding outlier payments, CMS proposes designating 0.36 percent of the 2.0 percent outlier target amount (or .0072 percent of total OPPS payments) to pay for CMHC outlier claims. **The AHA does not support dividing the outlier pool or creating two separate outlier thresholds, and will urge CMS not to move forward with this significant policy change in the final rule.**

Due to revised simulations on the new claims data and policy changes described above, the agency is proposing to increase the outlier payment percentage to both hospitals and CMHCs to 50 percent, up from 45 percent in 2003.

Elimination of Transitional Corridor Payments

By law, transitional outpatient corridor payments and rural hold harmless payments will expire December 31, 2003, except for payments to cancer and children's hospitals which are permanently protected. In the rule, the agency states it is concerned about the impact that losing these funds would have on small rural hospitals, and invites comments on whether CMS should increase payment rates – in a budget neutral manner – for clinic and emergency department (ED) visits for rural hospitals with less than 100 beds. The agency states that it has the authority under section 1833(t)(2)(E) of the Act to "establish in a budget neutral manner adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." **The AHA is concerned that <u>all</u> hospitals will be significantly harmed by the loss of hold harmless and transitional corridor payments, and will continue to urge Congress to extend these provisions for all providers with new money. Moreover, the AHA is concerned about differential payment rates and will push Congress to increase payments for clinic and emergency department visits for <u>all</u> providers.**

Evaluation and Management (E/M) Services

Since the implementation, hospitals have coded clinic and ED visits using the same current procedural terminology 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. Although hospitals were anticipating that CMS would propose a national, uniform E/M coding system in 2003, the agency chose not to do so. As a result, the AHA and the American Health Information Management Association convened an independent panel of experts to develop a set of coding guidelines for CMS. Specifically, the panel recommended that CMS should:

1. Make payment for emergency department and clinic visits based on four levels of care.
2. Create HCPCS codes to describe these levels of care as follows:
   - Gxxx1 – Level 1 Emergency Visit
   - Gxxx2 – Level 2 Emergency Visit
   - Gxxx3 – Level 3 Emergency Visit
   - Gxxx4 – Critical Care provided in the Emergency Department
   - Gxxx5 – Level 1 Clinic Visit
   - Gxxx6 – Level 2 Clinic Visit
   - Gxxx7 – Level 3 Clinic Visit
   - Gxxx8 – Critical Care provided in the Clinic
3. Replace all the HCPCS currently in APCs 600, 601, 602, 610, 611, 612, and 620 with GXXX1 through GXXX8.
4. Crosswalk payments from GXXX1 to APC 610, GXXX2 to APC 611, etc.

CMS said it is currently considering proposed national coding guidelines recommended by the panel, and, upon completion, plan to make any proposed guidelines available on the OPPS Web site for public comment. CMS also proposes to implement new E/M codes only when it is also able to implement guidelines for their use. This guidance will be issued after ample opportunity for public comment, systems change and provider education**. We believe that these E/M coding recommendations will meet hospitals' needs. And, while we support CMS' proposal to give providers the time necessary to implement new provisions, we are concerned that continued use of current codes after October 16, 2003 may be in conflict with the Health Insurance Portability and Accountability Act. The AHA will urge CMS to issue guidance to address this potential problem.**

Observation Services

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure, chest pain and asthma. The agency currently is not proposing any changes for observation services, and is not seeking public comment on observation issues. However, at the January 2003 meeting of the Advisory Panel on APC Groups, the Panel established an observation subcommittee tasked to review International Classification of Disease Codes, clinical modification codes, and operational issues related to observation. The subcommittee will report its findings back to the Panel in January 2004.

Inpatient Only Procedures

The rule proposes to retain its inpatient-only procedure list, which identifies services that are unable to receive payment if they are performed in an outpatient setting. The AHA 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.

Procedures Performed on an Emergency Basis

In the 2003, CMS implemented a new "modifier-CA," which identifies an inpatient-only procedure payable on an outpatient basis when it is performed emergently and the patient dies before admission. These services were paid using a new technology APC, but this has been problematic because payment under a new technology APC is a fixed amount with no relative payment weight and is, therefore, not subject to recalibration based on hospital costs. In the rule, CMS proposes to establish a new APC 375 for payment of these procedures, and invites comments on the proposed change.

Beneficiary Coinsurance

By statute, the 2004 national unadjusted beneficiary coinsurance for an APC may be no more than 50 percent of the APC payment rate, down from 55 percent in 2003. In addition, CMS is proposing slight clarifications to its copayment methodology when payments for APC groups change because of recalibrated APC relative weights.

Financial Impact on Hospitals

CMS estimates that implementing the rule's changes will result in the following per-case change in payment from 2003 to 2004 – excluding the impact of changes to hold harmless, corridor,

outlier and transitional pass-through payments, which would collectively reduce per case payments:

All Hospitals	**3.8%**
Urban Hospitals	3.7 %
Large Urban	3.8 %
Other Urban	3.7 %
Rural	4.0 %

Comments

The AHA will submit a comment letter to CMS on many of the proposed changes in the 2004 outpatient PPS rule and urge you to do the same. A sample letter will be posted soon at www.aha.org that may help as you prepare your comments. All comments are due to CMS by **October 6.**

Mail written comments (an original and two copies) to the following address:

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