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Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates (70 *Federal Register* 42673), July 25, 2005.

Dear Dr. McClellan:

On behalf of our 4,800 member hospitals, health care systems, and other health care organizations, and our 33,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (OPPS) for calendar year 2006.

Our analysis of the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2006 than in 2005. These changes make it extremely difficult for hospitals to plan and budget from year to year. Among these "broken" APCs, several evaluation and management (E/M) services APCs – especially clinic visits – continue to experience declines in payment rates. We would expect that four years after the start of the OPPS, the payment rates and associated payment-to-cost ratios would be much more stable.

In addition to this instability, the entire OPPS is underfunded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues such as severe workforce shortages, skyrocketing liability premiums, the rising cost of drugs and technologies, aging facilities, expensive regulatory mandates and more. **The AHA will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.**

The proposed rule contains a number of significant policy changes, including changes to payments for handling costs hospitals incur for separately paid drugs, increases in the threshold for the outlier policy, reduced payments for multiple imaging procedures, and changes to payment for rural hospitals. We address these areas briefly in this cover letter and in more detail in the attachment.

PHARMACY OVERHEAD AND DRUG HANDLING PAYMENT RATE ADJUSTMENT

The proposed rule adjusts the APC rates for separately payable drugs to take into account pharmacy overhead and drug handling costs. Since CMS does not have separate hospital charge data on these pharmacy costs, the agency proposes in 2006 to pay 2 percent of the average sales price (ASP) for these products. To set payment rates in the future, CMS proposes three distinct temporary healthcare common procedure coding system (HCPCS) codes (C-codes) and corresponding APCs to differentiate by level of overhead costs for drugs and biologicals. Hospitals would be instructed to charge the appropriate pharmacy overhead C-code when they provide separately payable drugs.

The AHA believes that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We are concerned, however, that the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. **CMS should freeze payments at 2005 levels for those drugs whose payments would decline significantly from the 2005 rates, particularly for those drugs that may have especially complex and costly handling requirements.** We also have serious operational concerns about the requirement that hospitals establish separate charges for pharmacy overhead using the three proposed C-codes. Most importantly, Medicare providers must have uniform charges for all payers (see 70 *Federal Register* 42693), but payers other than Medicare do not use the C-codes. If implemented, this policy would seem to be inconsistent with the requirement stated in the *Federal Register* that "Medicare providers are required to maintain uniform charges for all payers" because providers would now be obligated to maintain different charge structures for drugs – one for Medicare that does not include handling costs and one for other payers that does.

For this and many other reasons outlined in our detailed comments, the **AHA strongly opposes CMS' proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs using the three proposed C-codes.** Instead, we recommend that CMS work with stakeholder groups to collect further data and develop simpler solutions. The AHA would be pleased to convene a group of member hospitals to discuss possible alternatives.

OUTLIER POLICY

The AHA also continues to be concerned about the outlier policy. The proposed rule would decrease the set-aside for outlier payments from 2 to 1 percent and increase the dollar threshold for receiving outlier payments by $400, to $1,575. We are concerned about whether the proposed threshold is too high and request clarification on how it was determined. In addition, as in previous years, the proposed rule does not include data on the actual outlier payments made in 2005 and prior years. **The AHA strongly recommends that CMS publish in the final rule data on actual outlier payments made in 2004 and prior years, and that actual outlier payments for 2005 and later years be reported as soon as possible.**

REDUCED PAYMENT FOR MULTIPLE IMAGING PROCEDURES

CMS proposes reducing payment when multiple imaging services are provided on the same day, with full payment for the costliest imaging service and a 50 percent reduction in payment for additional procedures from the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area. In developing this policy, CMS did not examine hospital cost data, but relied on Medicare physician fee schedule practice expense data. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies obtained by hospitals, if they even exist.

The AHA opposes moving forward with this policy without a better justification and more substantial, hospital-based data to support the policy. We would note that the APC advisory panel came to the same conclusion. We also are concerned with the lack of implementation detail provided in the proposed rule, such as defining "the same session." Finally, we would like clarification on how CMS would ensure that this change is budget neutral. The proposed rule provides no detail on how the impact of the multiple imaging procedures discount was calculated or how the budget neutrality factor was adjusted.

CHANGES TO PAYMENTS FOR RURAL HOSPITALS

The proposed rule announces the expiration of hold-harmless payments for small rural hospitals. These are vulnerable facilities that provide important access to care for their communities. The AHA is working with key members of Congress on legislation to permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

The proposed rule also presents the findings of a study on rural versus urban hospital outpatient costs, and concludes that a 6.6 percent payment increase is needed for rural sole community hospitals (SCHs). The AHA is concerned that the supporting analysis in Table 6 of the proposed rule does not separately present findings for rural hospitals with 100 or fewer beds that are not rural SCHs. **We urge CMS to present its findings for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.** The AHA also seeks clarification on whether the 6.6 percent payment increase is affected by hospital reclassifications or participation in the Rural Community Hospital (RCH) demonstration program.

The attached detailed comments on the proposed changes expand on the points raised above and also on several other important parts of the rule.

The AHA appreciates the opportunity to comment. If you have questions please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273.

Sincerely,

Rick Pollack
Executive Vice President

Attachment

American Hospital Association

Attachment
OPPS Comment Letter
September 16, 2005

Detailed Comments on the Proposed Rule for the 2006 Outpatient Prospective Payment System

APC RELATIVE WEIGHTS

Current law requires that the Centers for Medicare & Medicaid Services (CMS) review and revise the relative payment weights for ambulatory payment classifications (APC) at least annually. The American Hospital Association (AHA) continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates as this information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the August 2000 implementation of the outpatient prospective payment system (OPPS), payment rates for specific APCs have fluctuated dramatically. For 2006, the proposed rates continue to show significant volatility for several reasons.

First, in the proposed rule, CMS uses the most recent claims data for outpatient services to set 2006 weights or rates, using approximately 49 million whole claims for hospital outpatient department services furnished during calendar year 2004 to create 81 million single records. **The AHA continues to support the use of the most recent claims and cost report data to set the 2006 payment weights and rates.**

Second, CMS continues its efforts to include more claims data in the calculation of the APC payment rates, especially those "multiple procedure claims" that contain charges for more than one service or procedure. CMS is proposing to expand the number of Healthcare Common Procedure Coding System (HCPCS) codes it bypasses on a claim – from 383 in 2005 to 404 in 2006 – so that "pseudo" single-procedure claims are created. This list of bypassed codes was developed using an empirical approach established in 2005 and described in the rule. CMS also proposes to continue using "date of service matching" – in which charges are attributed to separately payable HCPCS codes based on the code's date of service – as a tool for creation of "pseudo" single claims. **In general, the AHA continues to support the use of multi-procedure claims, as we believe that these data improve hospital cost estimates. The AHA supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures. We also continue to support the use of "date of service matching" in developing the 2006 outpatient rates.**

The AHA is concerned, however, that while the proposed rule provides a detailed description of the methodology used to calculate the APC weights, it does not provide adequate information for hospitals to evaluate the impact of each of the proposed policy changes independently or in combination. Questions such as, "What would the weights be without the changes?" and "How much of the volatility in the weights is due to the changes?" cannot be answered due to this lack of data**. The AHA requests that CMS**

provide a public use file that shows the impact of each individual proposed change in methodology so that health care providers can review the file to determine how the changes would affect their own operations, and provide a basis for submitting thoughtful comments to CMS.

In addition, although we understand the empirical criteria used to determine the additional codes to add to the bypass list, we find it puzzling that the bypass list includes only some office visit and consultation services codes. For instance, the list includes HCPCS codes 99213 and 99214, but not 99211, 99212, and 99215. One could speculate that this might be explained, in part, by the continuing lack of consistency across hospitals in the use of the evaluation and management (E/M) codes due to the absence of uniform guidelines for hospital coding of E/M services. **The AHA seeks clarification regarding why only some of the office visit and consultation service E/M codes are included in the bypass list.**

Proposed Changes to Packaged Services: The AHA commends CMS and the APC Panel's Packaging Subcommittee for initiating a process to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. When hospitals provide services described by these "N" status codes alone, there is no way to be reimbursed for the costs of providing these services. **We strongly encourage CMS to continue to work with the APC Panel's Packaging Subcommittee to further review "N" status codes and identify those that should be paid separately.**

PARTIAL HOSPITALIZATION

The AHA is concerned that the proposed 15 percent reduction in the per diem payment rate for partial hospitalization services could dramatically harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. These services already are quite vulnerable, with many programs in recent years closing or limiting the number of patients they can accept.

We share CMS's concern about volatility of the community mental health center (CMHC) data and support the agency's intent to monitor CMHC costs and charges for these services, and work with CMHCs to improve their cost reporting so that payments can be calculated based on better empirical data.

Although the AHA recognizes that CMS made the proposal to avoid at a later time an even more significant reduction in the payment rate for these services, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services. Instead, the AHA recommends that in the final rule for 2006, CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

CONVERSION FACTOR

The AHA assumes that CMS again will follow the practice it has used in previous years of utilizing the same market basket update published in the inpatient PPS final rule for the purposes of the outpatient PPS. In the inpatient final rule for FY 2006, CMS responded to an AHA request and changed the market basket estimation methodology to provide a better estimate of hospitals' cost increases. We assume that this change also will be part of the final outpatient rule.

EXPIRING HOLD HARMLESS PROVISION FOR TRANSITIONAL CORRIDOR PAYMENTS FOR CERTAIN RURAL HOSPITALS

The AHA is concerned about the impact that the expiration of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. The AHA is working with Congress on legislation to permanently extend hold harmless payments to small rural hospitals and rural sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

RURAL HOSPITAL ADJUSTMENT

In the proposed rule, CMS discusses the study the agency conducted, in compliance with Section 411 of the Medicare Modernization Act (MMA), to determine whether rural hospital outpatient costs exceed urban hospital outpatient costs. CMS noted that it conducted an explanatory regression analysis that included three specific classes of rural hospitals – rural sole community hospitals (SCHs), rural hospitals with fewer than 100 beds that are not rural SCHs, and other rural hospitals. CMS conducted this analysis to determine whether the small difference in costs found between rural versus urban hospitals in the initial regression analysis was uniform across rural hospitals or whether all of the variation was attributable to a specific class of rural hospitals. The results of this explanatory regression analysis led CMS to conclude that rural SCHs are more costly than urban hospitals. Therefore CMS proposes to provide a 6.6 percent payment increase for rural SCHs for 2006.

The AHA is concerned that Table 6 in the proposed rule, which includes the results of this analysis, does not separate the regression results for rural hospitals with 100 or fewer beds that are not rural SCHs. While CMS implies in the preamble that the results for this category of hospitals were not significant, we believe it is important to report the results for these hospitals, as they will be the facilities that will lose their hold-harmless protection in 2006. **Therefore, we urge that in the final rule, CMS either present in Table 6 the regression results for rural hospitals with 100 or fewer beds that are not SCHs or explain why they cannot report these results.**

The AHA also seeks clarification on three issues: (1) Would a SCH located in a rural area, which has been reclassified for wage index purposes into an urban area, be eligible for the SCH adjustment? (2) Would a SCH located in an urban area, which has been reclassified for wage index purposes into a rural area, be eligible for the SCH

adjustment? (3) Would rural SCHs participating in the Rural Community Hospital (RCH) demonstration program be eligible for this adjustment?

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospitals' losses when treating high-cost cases. For 2006, CMS proposes reducing the outlier pool to 1 percent of total outpatient PPS payments. Further, CMS says that the fixed-dollar threshold should be increased by $400, to $1,575, to ensure that estimated 2006 outlier payments would equal 1 percent of total outpatient PPS payments. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,575 more than the APC rate.

While the AHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, we are concerned that CMS has set the thresholds for outliers in this rule too high. The AHA seeks further clarification from CMS regarding how the agency determined that a $400 increase in the fixed-dollar threshold was appropriate and how the $1,575 fixed-dollar threshold was calculated.

In addition, for the past four years, CMS set aside 2 percent of total estimated outpatient PPS payments to fund outlier payments to hospitals. For 2006, CMS is proposing to set aside only 1 percent for outliers. However, CMS does not publicly release in the *Federal Register* or on the CMS Web site data about how much of the outlier set-aside was actually spent in prior years. With the significant changes to outlier policies proposed for 2006, the AHA is concerned that Medicare may not actually spend the outlier target set-aside.

The AHA strongly recommends that in the final rule CMS publish data on actual outlier payments made in 2004 and prior years, that actual outlier payments for 2005 be reported as soon as CMS is able to obtain complete data, and that CMS continue to report this data into the future. If CMS is able to obtain this information on the inpatient side and publicly report it, it should be similarly obtained and reported on the outpatient side. Interested parties should not have to purchase costly databases in order to determine whether these thresholds are being set at the right level. Even if CMS believes that it does not have a statutory mandate to return unspent outlier pool funds to the outpatient PPS system, we believe that CMS has a duty to make appropriate estimates, and we are concerned that CMS cannot set the outlier threshold at an appropriate level if it does not know the actual outlier spending.

In issuing a public accounting of total outlier payments for 2005, CMS will need to take into consideration the implications of an error that occurred in identifying services that qualified for outlier payments. CMS incorrectly set the outlier threshold too high in the 2005 fiscal intermediary system, which resulted in underpayment for outliers. Providers were requested to identify and re-bill those claims that should have received outlier

payments. These additional outlier payments should be considered in its calculation of actual outlier expenditures for 2005.

NEW TECHNOLOGY

The AHA supports CMS's proposal to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA's) CPT Editorial Panel before CMS accepts a New Technology APC application for review.

As we have noted in prior comment letters and verbally before the APC Advisory Panel, the proliferation of G-codes and C-codes and their potentially overlapping descriptions with CPT codes is confusing and burdensome for hospital coders. This confusion often has resulted in incorrect coding and unreliable data available for rate setting. Requiring that an application for a new CPT code be submitted at the time of a New Technology APC application will minimize the need for expedited issuance of temporary G- or C-codes. HCPCS level II G- and C-codes generally are not accepted by payers other than Medicare, thus requiring hospitals to have two different codes to report the same procedure, depending on the payer. This new process will reduce the duplication of codes so that it will start the process correctly via CPT, rather than with a New Technology assignment and no way to report the procedure. While we understand that circumstances may exist when a G- or C-code still will be required, having a CPT code available for new technology will simplify the billing and coding process for hospitals because one set of codes (i.e. CPT) will be used as much as possible for all payers.

Device manufacturers may not be planning ahead and applying for CPT codes for a variety of reasons, including fear of application denial. In any event, the CPT process involves a more rigorous process than level II HCPCS codes and includes the opportunity for input from the physician specialty societies. Without support from the physician specialties that would embrace the new technology, it is doubtful that the new technology will achieve acceptance from the medical community. Input from the physician community also ensures that the code descriptor selected for new technology procedures will be as close as possible to the terminology that physicians will use to document these services. This in turn will reduce the confusion in determining proper code selection.

HYPERBARIC OXYGEN

The AHA supports CMS's decision to no longer use the respiratory therapy cost-to-charge ratio (CCR) for purposes of calculating the median cost for hyperbaric oxygen therapy (HBOT), and instead use the hospital's overall CCR. Since some hospitals, though, currently report HBOT costs on a separate line on their cost report, the AHA would recommend that in 2006, CMS should calculate the median rate for HBOT using the HBOT CCR for hospitals that report separately. If hospitals do not separately report HBOT, then the overall hospital CCR would be used. In order to develop more accurate rates for HBOT in the future, CMS should encourage hospitals to report the HBOT costs on a separate HBOT line on their cost report. This should not be administratively

difficult for hospitals because HBOT revenues already are captured in a specific separate revenue code, and would involve only a change in where costs for HBOT are reported on the cost report.

NON-PASS-THROUGHS

The MMA requires that in 2006, payment for specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to any adjustment for overhead costs. In the proposed rule, CMS evaluates three alternatives for setting 2006 payment rates for these drugs: (1) average and median purchase price data for drugs purchased from July 1, 2003 to June 30, 2004 derived from a General Accountability Office survey of 1,157 hospitals; (2) the average sales price (ASP) data from the fourth quarter of 2004; and (3) mean and median costs derived from the 2004 hospital claims data. After considering the merits and weaknesses of each approach, CMS proposes to pay ASP+6 percent for separately payable drugs and biologicals in 2006.

In general, the AHA supports this proposal and agrees that paying for drugs at ASP+6 percent appears to be the best available estimate of average acquisition cost. This also has the additional benefit of providing for consistent payment rates across the hospital outpatient PPS and the physician fee schedule payment systems. Finally, given the inflation in drug prices over time, we believe that the ability to update ASP rates on a quarterly basis also is a key advantage of this proposal. However, the proposal to pay at ASP+6 percent will result in significant reductions in payments for some separately payable drugs and biologicals**.**

Therefore, the AHA supports the APC Panel's recommendation that CMS carefully track the drug codes to be paid at ASP+6 percent, with a particular focus on drugs with rates that would fall significantly in 2006. We are concerned that steep drops in payments for certain drugs and biologicals could have implications on manufacturer production levels of these drugs and hurt patient access to some drug therapies. If CMS obtains evidence that access to certain drug therapies would be threatened due to payment rate decreases, then it should consider freezing payments or otherwise limiting decline in payments for these products.

Pharmacy overhead and drug handling adjustment: In the proposed rule, CMS took into consideration the Medicare Payment Advisory Commission (MedPAC) recommendations on how to adjust the APC rates for separately payable drugs to account for pharmacy overhead and drug handling costs. To address this, CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories. This will differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy C-code for overhead costs associated with the administration of each separately payable drug and biological based on the code description that best reflects the service the hospital provides in preparing to administer the product. Since CMS does not have separate hospital charge data on pharmacy overhead, the agency proposes for 2006 to pay for these costs based on 2 percent of the ASP. This would result in overall drug payments, including the drug itself and the associated handling

payment, of ASP+8 percent, which CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

The AHA agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We are concerned, however, that the ASP+2 percent adjustment for drug handling is not adequate for certain drugs that have very high handling costs due to special equipment or procedures related to the drug's toxicity, or special compounding or preparation requirements. As noted above, we recommend that CMS consider freezing payments in 2006 for those drugs whose payments would decline significantly from the 2005 rates, particularly for drugs that may have especially complex and costly handling requirements. In the future, CMS should work with hospital and pharmacy stakeholders to establish differential add-on payments for drug handling costs for a wide variety of drug handling categories.

The AHA strongly opposes CMS' proposal requiring hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals, and utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome and difficult for hospitals to implement.

There are many complex issues and administratively burdensome aspects to adopting CMS' proposal for charging for drug handling through the use of these new C-codes. The most important is that, if implemented, this policy would seem to be inconsistent with the requirement that Medicare providers maintain uniform charges for all payers (see 70 *Federal Register* 42693). Given this, it is impossible to charge Medicare a rate that does not reflect handling costs, and charge other payers for the same drug a higher rate that does reflect handling costs. This simply could not be done. Even assuming that hospitals could provide differential charges, other concerns remain:

- Hospitals would have to evaluate the normal mark-up formula for all pharmacy items and deduct the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug. This would be an extremely complex and time-consuming process.
- For each separately payable drug, hospitals would need to assign the handling charge to one of CMS's proposed new drug handling C-codes. These C-codes are only recognized by and acceptable to Medicare, but not to other payers. Hospitals therefore would have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims, but bill them as a single line item for other payers. Setting aside the concern raised above about violating the Medicare requirement for uniform charges, this also introduces another level of complexity and burden.
- Confusion exists about how the drug handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient. Would the hospital report a single C-code for handling costs in this case or multiple C-

codes? Confusion around how to charge could result in incorrect data, which would make it difficult to establish appropriate future payment rates for these services.

- Drug pricing is generated through a pharmacy charging system often located outside the hospital's normal charging system, and may not be able to accommodate CMS' proposed C-codes.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, it is unclear how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

The AHA also is aware that the APC Panel, based on testimony provided by a number of organizations representing drug manufacturers and others, has proposed that CMS expand the application of its proposed drug handling coding and payment methodology to drugs that are packaged into other APCs. **The AHA strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes**. In addition, hospitals generally do not provide detailed billing for drugs that are not separately paid, meaning that hospitals do not separately assign HCPCS C-codes or J-codes for these drugs. More importantly, not all drugs have C-codes or J-codes. Creating new codes for all drugs would be a significant burden. It would therefore be extremely difficult for hospitals to bill the right drug handling C-code for packaged drugs. Further, many hospitals that have adopted a paperless billing system also use an imaging system to generate a bill for a patient. Given the large volume of drugs used in hospital outpatient departments, expanding the drug handling coding requirements to all these drugs, regardless of their packaging status, would dramatically increase hospital administrative costs associated with this already misguided proposal.

The AHA strongly recommends that CMS *not* implement the proposed drug handling C-codes in 2006. Instead, we recommend that CMS work with stakeholder groups to collect additional data, and develop alternative and simpler solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs. Such an approach should incorporate the payments for drug handling directly into the payment rate for the drug itself, rather than requiring separate coding systems. The AHA would be pleased to convene a group of member hospitals to work with CMS and with the APC Advisory Panel to discuss possible alternatives.

If CMS decides to implement this burdensome drug handling C-codes policy, then AHA strongly suggests that CMS provide a grace period of no less than 6 months after implementation of the 2006 outpatient PPS (June 1, 2006) so that hospitals can create the new charging system, make system changes and educate pharmacy staff, hospital finance staff, and coders on the required use of the drug handling "C" codes.

DRUG ADMINISTRATION

The AHA continues to support CMS' proposal to use CPT codes to bill for drug administration services provided in the hospital outpatient department. Using CPT codes simplifies the administrative burden for the coding of drug administration since hospitals can use the same codes for Medicare and non-Medicare payers. We understand that under the proposed methodology, payment for services within the same APC would be collapsed by the outpatient code editor (OCE) into a single per-visit APC payment – just as it currently does – until 2005 claims data become available, when CMS will provide further refinement and recognize resources associated with drug administrations that last several hours.

Because of the significant changes expected with the new 2006 CPT codes for drug administration, hospitals will need instruction and clarification on the application of these new codes. For example, clarification will be needed regarding the following:

- How the code application may be similar or different for the hospital outpatient department as compared to the physician setting—especially for non-oncology providers of infusion and injection services, since they often cross departments.
- Definitions of what constitutes an "initial" vs. subsequent infusion vs. concurrent infusion.
- Definition of "hydration" and how it is different from a hydration that is given for therapeutic reasons. In other words, a therapeutic infusion can be hydration.
- How should infusions or titrations be reported? Many times they are established with a documented start time and administered via pump. As such, many infusions are maintained by equipment function rather than manual intervention. In these cases, a nurse may be aware of the start time of an infusion and may document it. It is unlikely, though, that the stop time will be documented.

The AHA welcomes the opportunity to work with CMS on coding education, as well as on the development of appropriate future rates for drug administration in hospital outpatient departments.

E/M SERVICES

Since the implementation of the outpatient PPS, hospitals have coded clinic and emergency department (ED) visits using the same 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. 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, in 2003 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.

In the 2004 and 2005 OPPS rules, CMS stated it would consider national coding guidelines recommended by the panel, and planned to post for public comment the proposed guidelines on the outpatient PPS Web site. CMS also proposed to implement new E/M codes only when it could also implement guidelines for their use. This guidance would be issued after ample opportunity for public comment, systems change and provider education.

The AHA is disappointed that the 2006 proposed rule fails to include national guidelines for facility E/M reporting. While we applaud CMS as the agency continues to develop and test the new codes, hospitals still are without a standard methodology for reporting E/M services. This lack of uniformity not only puts hospitals at compliance risk for multiple interpretations of the level of service that should be coded and billed, but also affects CMS' ability to gather consistent, meaningful data on services provided in the emergency department and hospital clinics. This is especially important because CMS uses the mid-level clinic visit (APC 601) as the anchor for establishing the relative weights within the outpatient PPS, and, due to a lack of national coding guidelines, there is no agreement on what a mid-level clinic visit encompasses. We believe that the E/M coding recommendations made by the independent panel will adequately meet hospitals' needs.

BLOOD AND BLOOD PRODUCTS

CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a decrease of more than 10 percent in comparison to their 2005 payment medians, CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood

product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition costs, most notably for leukocyte-reduced red blood cells. With the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, the AHA recommends that CMS set 2006 rates at *the greater of*: the simulated medians calculated using the 2004 claims data; or the 2005 APC payment medians for these products.

The AHA also commends CMS for issuing in March 2005 comprehensive and clear billing guidelines for blood and blood products, addressing issues such as the blood deductible and differences between donor and non-donor states. This document was well received by hospitals, and it should help clear up much of the confusion regarding the correct way to code and bill for blood and blood products. The AHA will continue to work with and educate our member hospitals, using CMS' blood billing guidelines about appropriate blood coding and billing practices.

OBSERVATION SERVICES

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain and asthma. To reduce the administrative burden on hospitals attempting to differentiate between packaged and separately payable observation services, CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). CMS would shift determination of whether observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

The AHA supports the concept of allowing the OCE logic to determine whether services are separately payable. This will result in a simpler and less burdensome process for ensuring payment for covered outpatient observation services. As we stated in the hospital outpatient PPS in 2003, the existing G codes for observation services, with their long, complex descriptors that encompass all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are very pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

However, we believe that the OCE logic could be used even more efficiently to make the HCPCS code GYYYY unnecessary. If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center)

revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through the ED or urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission, and pay accordingly.

Further, the AHA seeks clarification on the reference to inpatient status on page 42743 in the proposed rule that states "That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to 'observation status,' regardless of the patient's status as an *inpatient* [emphasis added] or outpatient." We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

INPATIENT PROCEDURES

CMS proposes to remove 25 codes from the "inpatient only" list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The AHA continues to urge CMS to eliminate the "inpatient only" list. Physicians, not hospitals, determine where procedures can be performed safely, as well as whether a patient's condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, then under current rules the hospital is penalized if that procedure happens to be on the "inpatient only" list.

If the "inpatient only" list is not eliminated for 2006, CMS should consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the "inpatient only" list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

ANCILLARY OUTPATIENT SERVICES

In the proposed rule, CMS expresses concern about the increase in the volume of hospital claims that are billed with the –CA modifier from 2003-2004, growing from 18 to 300 claims over that one year. This modifier was initially used in 2003 to address situations where a procedure on the "inpatient only" list must be performed to resuscitate or stabilize a patient in a hospital outpatient department with an emergency, life-threatening condition and the patient dies before being admitted as an inpatient. In addition, CMS states that a clinical review of the claims reported using this modifier support their concerns regarding the increased modifier volume and hospitals' possible incorrect use of the modifier for services that do not meet the payment conditions CMS established.

The AHA agrees that the –CA modifier should be used only in rare circumstances. It is unclear why CMS has seen such a substantial increase in the use of the –CA modifier. It could be that hospitals are using the modifier incorrectly, or that, because it is a relatively new modifier, hospitals were only recently aware of it. In addition, there may be circumstances to explain why few of the claims also include a clinic or emergency department visit on the same date of service as the procedure appended with a –CA modifier. For example, a Medicare beneficiary arrives for a scheduled procedure and, due to complications, the physician finds it necessary to provide a service that they had not otherwise intended to perform in an outpatient setting, and the patient dies prior to admission.

The AHA believes that the –CA modifier policy supports an important function for hospitals and should be preserved. However, it appears that hospitals would benefit from additional education on the appropriate use of the –CA modifier. **In collaboration with CMS, the AHA will provide further education to hospitals through its Coding Clinic publication.** In addition, we support CMS' continuing to closely monitor hospital use of this modifier.

MULTIPLE DIAGNOSTIC IMAGING PROCEDURES

CMS proposes reducing payment when multiple imaging services are provided on the same day. In accordance with a MedPAC recommendation CMS proposes to make full payment for the highest paid imaging service and pay 50 percent of the APC payment rate for every additional procedure within the same "family" of procedures performed in the same session. The proposed rule outlines 11 "families" of imaging procedures by imaging modality and by contiguous body area.

The AHA opposes implementation of this policy without better justification and more substantial, supporting hospital-based data. In developing this policy, CMS did not examine hospital cost data. Rather, the agency relied on Medicare physician fee schedule practice expense data to determine the level of the discount. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the right level of efficiencies, if they exist.

Furthermore, CMS uses different methods to set payments in physician offices and hospital outpatient departments. The physician fee schedules are based on expert opinion of the resources required to perform different services while the outpatient rates are set based on hospital cost data. Hospitals conduct imaging procedures in unique circumstances not found in physician offices, such as in EDs and urgent care circumstances. **We urge CMS to conduct analyses using hospital data before implementing this policy.**

In addition, hospital cost data already may reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures. CMS determines the median cost for outpatient services by multiplying the charges on the

claim by the appropriate hospital department's cost-to-charge ratio (CCR). And while costs may be lower when multiple imaging studies are performed during the same session, most hospitals do not reduce their charges when more than one imaging service is performed in the same encounter. The hospital's CCR would therefore be lower than it should be because the denominator (charges) is higher than it otherwise would be if the hospital had charged less for the subsequent imaging studies. This results in a cost determination at the individual service level that is too low for single imaging studies, and too high for subsequent imaging studies. Because hospitals do both single and multiple imaging studies, the overall payments may be appropriate as they currently are calculated. **However, CMS's proposal to discount payments for subsequent imaging studies performed during the same encounter would underpay for both single procedures and for the highest rate APC when multiple imaging procedures are performed and reduce payment for other imaging services provided.**

We are also concerned with how this policy will be implemented and the lack of detail provided in the proposed rule, such as defining "the same session." During a suite of tests or an emergency stay, a patient may have an imaging procedure done in the morning, followed by medical review or other tests that indicate the need for a procedure from the same "family" later in the day. In this case, the tests would not be performed at the same time, or perhaps even in the same part of the hospital, and would be incorrectly subject to the discount. The APC advisory panel rejected the use of modifier 59 (separate procedure) for this purpose as too burdensome because it would require hospitals to track patients through the course of a day.

Finally, the proposed rule states that this policy will be budget neutral. However, no detail is provided on how the impact of the multiple imaging procedures discount was estimated or how the budget neutrality factor was adjusted to account for this. What share of imaging procedures did CMS estimate to be multiple imaging procedures? How were they defined? Will CMS analyze the data later to see if the estimates were correct?

In conclusion, the AHA agrees with the APC advisory panel recommendation that this policy should not be implemented without additional analysis and better substantiation.

INTERRUPTED PROCEDURES

CMS proposed to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted for clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs actually may increase, not decrease, as the clinical team addresses the patient's needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, many of the hospital's costs already will have been incurred. For example, the operating room will have been occupied during the start of

the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and either will be disposed or be reprocessed at additional cost.

Before CMS reduces payments for procedures billed using these modifiers, evidence must support both the need for and the level of those reductions.

PHYSICIAN OVERSIGHT OF NONPHYSICIAN PRACTITIONERS

The AHA supports CMS's proposal to defer to state law regarding the need for physicians to review and sign the medical records for outpatients cared for by nonphysician practitioners in critical access hospitals (CAHs). However, we also recommend that CMS extend the application of this policy to physician review of inpatient records for patients cared for by nonphysician practitioners. If state law permits these practitioners to practice independently, CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that state laws providing independent practice authority generate sufficient control and oversight of these nonphysician practitioners, and we do not believe that nonphysician practitioners reduce quality of care

The AHA also supports the additional flexibility CMS adds under this proposed policy for those states that do not allow for independent practice of nonphysician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.