American Hospital Association

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September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1392-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (Vol. 72, No. 148), August 2, 2007.

Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar (CY) 2008 outpatient prospective payment system (OPPS).

The AHA is commenting on several OPPS proposals. Most importantly, we have serious concerns about the proposed packaging rules, partial hospitalization payment (PHP) cuts, changes to the critical access hospital (CAH) conditions of participation, separate billing for pharmacy overhead costs and requirements for outpatient quality measure reporting. In brief, the AHA makes the following recommendations:

- CMS should re-evaluate its new packaging proposal. We found problems in CMS' methodology and correcting these problems leads to different impact results by type of hospital. If CMS decides to move forward with its proposal, we urge CMS to exclude observation services from its final packaging strategy at this time. The AHA supports the continuation of separately payable status for observation services.

- CMS should maintain the PHP per diem at the CY 2007 rate of $233 to ensure continued beneficiary access to PHP services. In addition, we recommend CMS further study the possibility of differentiating payment based on the intensity of services provided during a day of PHP services for CY 2009.

- CMS should rescind its proposal to require a CAH-operated provider-based facility created after January 1, 2008 to comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). The agency's proposal is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Such a policy would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

- CMS should withdraw its proposal instructing hospitals to bill separately the pharmacy overhead charge. The agency's proposal creates a huge administrative burden on hospitals and a morass of complexity that is unnecessary and excessive. Moreover, CMS should re-evaluate the recommendations of the Ambulatory Patient Classification Panel and consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs.

- CMS needs to refine several aspects of its new OPPS quality reporting program. First, the agency proposes to use the 10 outpatient measures that have received preliminary approval from the Hospital Quality Alliance (HQA) as the initial measures. We are pleased that CMS continues to align its choice of measures with the work of the HQA in the implementation of the hospital quality reporting programs; however, the HQA has only preliminarily approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. Therefore, we urge CMS to delay data collection until the measures have been thoroughly field-tested and received NQF endorsement, the data specifications have been finalized, and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in 2008 when the hospitals and vendors are fully prepared to commence the program.

  We also urge CMS to modify its validation approach for the outpatient reporting program. We believe that, for 2009, data validation may be conducted as a learning tool for hospitals, but there should be no minimum reliability threshold required for the annual payment update. In subsequent years, a reliability threshold may be established at a lower level and then gradually raised to 80 percent, similar to the approach for inpatient PPS quality reporting.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

The American Hospital Association's Detailed Comments on the Proposed Rule for the 2008 Outpatient Prospective Payment System

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OPPS: PACKAGED PROPOSAL

Increasing Packaged Services

The outpatient prospective payment system (OPPS), unlike other prospective payment systems, employs only moderate packaging of services and generally makes a separate payment for each individual service provided during a patient encounter.

For 2008, CMS proposes to broaden the OPPS payment groupings – ambulatory payment classifications (APCs) – by packaging into the primary service provided seven categories of items and services that CMS considers to be typically ancillary and supportive. These services are currently billed separately. The agency believes that payment based on a larger group of services will provide an incentive for hospitals to furnish services in the most efficient way by allowing them to manage their resources with maximum flexibility.

The seven categories of items and services CMS proposes to package into primary diagnostic and therapeutic procedures with which they are performed include:

- Guidance services,
- Image processing services,
- Intra-operative services,
- Imaging supervision and interpretation services,
- Diagnostic radiopharmaceuticals,
- Contrast media, and
- Observation services.

CMS proposes to assign packaged codes either a payment status indicator "N" or "Q." Status indicator "N" is assigned to those codes for services that are always integral to the performance of the primary service with which they are billed. The costs for these codes are always packaged. Status indicator "Q" is assigned to those codes that are usually, but not always, integral to a primary service. These codes may sometimes be paid separately when no other separately paid primary service is provided during the hospital outpatient encounter.

CMS notes that the median cost of many APCs will change not only as a result of the increased packaging itself but as a result of the changes it makes in individual codes moving into and out of the APCs.

The AHA generally has supported efforts to package more services into larger payment bundles. We believe, like CMS, that appropriately sized bundles can provide incentives to improve efficiency and manage resources. However, we have concerns about CMS' proposal and the underlying analysis behind it.

First, while the agency estimates that the proposal would redistribute approximately 1.2 percent of the 2007 expenditures under the OPPS, analyses prepared by The Moran Company indicate that the seven categories in CMS' proposal represent 6 percent of outpatient costs. The reason our analysis had a higher percentage of costs was because of the methodology for applying the status indicator "Q." The resulting impact reveals very different impacts by type of hospital than CMS' impact tables, and we are concerned that the implications of this policy are not fully understood.

Second, we have concerns about the proposal to package observation services. The billing and coding rules for observation have changed significantly since the implementation of the OPPS. Since CMS implemented separate payment for observation services in 2002 for selected medical conditions, hospitals have found the criteria and documentation requirements to be administratively burdensome and complex. During the past several years, the APC Advisory Panel has made multiple recommendations to CMS to simplify and/or clarify definitions and instructions for the reporting of observation services. Numerous operational hurdles had to be overcome to ensure compliance with all of the rules for reporting packaged observation charges versus separately payable observation APC charges. The requirements were not automated, difficult to track and involved multiple departments in order to ensure that the observation services were appropriate from both the clinical and billing perspectives. The confusion in billing observation led to incomplete data on separately billable observation services.

The impact of packaging observation at this time is likely to have the largest impact on those hospitals that understand and appropriately code for allowable observation services. Two hundred hospitals (or 5 percent) provided one-third of all separately payable observation services, according to The Moran Company's analysis of outpatient claims from 3,954 hospitals. Separately payable observation services are only covered for patients with three specific conditions: congestive heart failure, asthma and chest pain. These conditions are widely treated in the majority of America's hospitals and the concentration of observation services in a relatively small number of hospitals is likely due to the complexity and numerous changes of coding rules. To include observation services with such skewed claims data would be inappropriate at this time.

The AHA recommends that CMS re-evaluate its new packaging proposal in light of the methodological and data concerns. If the agency decides to move forward with its proposal, we urge CMS to exclude observation services from its final packaging strategy at this time. The AHA supports the continuation of separately payable status for observation services and CMS' use of the Outpatient Claims Editor logic to automatically determine whether observation services on a claim are separately payable. Begun in 2002, this process resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services and continuation of this policy will lead to improved understanding of observation services and costs.

Composite APCs

CMS proposes to create a "composite" APC that would pay a single rate for larger bundles of major, and currently, separately paid, services that are commonly performed in the same hospital outpatient encounter (or as part of a multi-day episode of care). CMS believes this concept of "composite" APCs would create incentives for greater efficiency.

The two composite APCs proposed for 2008 are:

- APC 8001 (Low Dose Rate (LDR) Prostate Brachytherapy Composite) and
- APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite).

CMS' proposal begins to address the concept of the outpatient "episode" of care, and these new bundles may offer a cohesiveness of payment similar to the cohesiveness of the care. While CMS expects to develop additional composite APCs in the future as it learns more about major services that are commonly provided together during the same hospital outpatient encounter, **the AHA urges CMS to evaluate closely the impact of these new bundles on payment adequacy and access to care before expanding this new policy to other services.**

OPPS: SPECIFIED COVERED OUTPATIENT DRUGS

The Medicare Modernization Act of 2003 (MMA) provisions require special classification and payment of certain separately paid drugs, biologicals and radiopharmaceuticals that had previously (or before December 31, 2002) received pass-through payments. In 2008, the law requires that payment for these specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs.

To set the proposed 2008 rates, CMS evaluated fourth quarter 2006 average sales price (ASP) data on about 500 drugs and mean costs derived from 2006 OPPS claims data. CMS concluded that using mean unit cost to set the payment rates for the drugs and biologicals would be roughly equivalent to basing their payment rates at ASP plus 5 percent. The agency cites findings from a 2005 Medicare Payment Advisory Commission (MedPAC) study of pharmacy overhead costs to support its conclusion that ASP plus 5 percent is a sufficient level to cover drug acquisition and pharmacy overhead costs. The MedPAC survey results indicated that hospitals set charge levels for drugs to cover both drug acquisition and pharmacy overhead costs.

For 2008, CMS proposes to pay for the drug acquisition *and* pharmacy overhead costs of specified covered outpatient drugs at a *combined* rate of ASP plus 5 percent. This rate is lower than the ASP plus 6 percent rate for drugs furnished in physician offices. Lowering the payment percentage from 6 to 5 percent above ASP is a budget-neutral change to the OPPS and redistributes the additional 1 percent of payments to other outpatient services. However, reducing payment for separately payable drugs under the OPPS, while maintaining drug payments at ASP plus 6 percent for drugs provided in physician offices, creates inconsistencies in payment that could result in unintended and inappropriate incentives to treat patients in one setting over another. CMS should eliminate the inconsistency of paying differently for the same drugs based on the treatment setting.

Pharmacy Overhead Costs

CMS proposes to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an uncoded revenue code line on the claim. This policy would apply to the reporting of charges for all drugs and biologicals, including contrast agents, regardless of the item's packaged or separately payable status. CMS would not apply this policy to radiopharmaceuticals because it has previously instructed hospitals to include the overhead and handling charges in the charges for the radiopharmaceutical products.

CMS believes that this change would allow the agency to identify pharmacy overhead costs for drugs and biologicals and, in future years when the 2008 claims data become available, to package these overhead costs into payment for the associated procedure, likely a drug administration procedure. CMS also believes that this policy would not violate the "uniform charge" regulation that prohibits hospitals from charging Medicare differently from all other payers because under this proposed policy the same total charges would be provided to all payers.

However, CMS' proposal creates a huge administrative burden on hospitals and an unnecessary morass of complexity. During November and December, thousands of drugs and dosages would need to be evaluated and examined for the resources they consume in the operations of the pharmacy. Even large hospitals with sophisticated staff, resources and information systems – let alone small and rural hospitals – would find this task and the related timeframes unworkable. Because of the enormity of this task, hospitals would be forced to apply simple across-the-board overhead percentages which would undermine the validity and usefulness of the data.

CMS has vastly underestimated the difficulty of its proposal. The agency should withdraw its proposal, re-evaluate the recommendations of the APC Panel and consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs.

OPPS: QUALITY DATA

The Tax Relief and Health Care Act of 2006 mandated that CMS establish a program under which hospitals must report data on the quality of hospital outpatient care to receive the full annual update to the OPPS payment rate, effective for payments beginning in CY 2009. Hospitals that fail to report outpatient quality data would incur a reduction in their annual outpatient payment update factor of 2.0 percentage points.

Quality Measures
To implement this legislative mandate, CMS proposes to use the 10 outpatient measures that have received preliminary approval from the Hospital Quality Alliance (HQA). We are pleased that CMS continues to align its choice of measures with the work of the HQA; however, the HQA has only *preliminarily* approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. We urge CMS to proceed in the same manner when the agency finalizes the rule.

Further, it is vital that all new measures undergo a rigorous field test to identify any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors. **We urge CMS to fund a thorough field test of the outpatient measures immediately.**

Regarding the other measures that CMS identifies for possible inclusion for CY 2010 or later, we reiterate our position that all measures included in hospital reporting programs should be NQF-endorsed and HQA-adopted.

Timing of Implementation
To be eligible for a full OPPS payment update in 2009, CMS proposes that hospitals submit quality data on these 10 measures effective with hospital outpatient services furnished on or after January 1, 2008. Before data collection can begin, hospitals will have to review the data specifications, become familiar with a new data collection tool, implement their reporting systems, develop any sampling methodologies and educate and train staff. Likewise, data vendors will have to develop the data abstraction and submission tools, test the software programs, create hospital educational materials and programs and work with hospitals to implement the software programs.

By contract and according to the CMS/Joint Commission Specifications Manual, data vendors are to have 120 days to complete this programming and prepare to collect the data. CMS released the data specifications for the outpatient measures on August 29; however, we understand that the specifications are still in fluctuation and may be changed as the measures go through NQF endorsement or are tested further. Developing the data collection tools and assisting hospitals with implementation by January 1 will be extremely challenging for the vendors; implementing these changes as the specifications are still evolving may be impossible.

Hospitals have told the AHA that the implementation timeline for outpatient reporting will be extremely difficult for them to meet, primarily due to the complexities around building the information technology infrastructure to begin data collection. The outpatient measures will require new documentation forms and criteria, and hospitals will face documentation issues that are different from those they have met for inpatient reporting. Hospital inpatient, emergency department and outpatient clinic information systems typically are separate from one another without common data interfaces. Even those hospitals with more established electronic health records may have different systems for inpatient and outpatient records, particularly with respect to outpatient clinic records. In addition, some data elements necessary for reporting will have to be obtained from billing records, similar to the inpatient measures. However, there currently is no mechanism available to collect this information from outpatient or physician claims.

Further, smaller hospitals may see their reporting burden increase dramatically with the implementation of the emergency department transfer measures. We generally applaud measures that allow smaller hospitals to fully participate, as many have been unable to report on some of the inpatient measures. However, these hospitals, which have fewer staff available and trained to abstract data and fewer resources to implement electronic systems, may be overwhelmed trying to implement reporting on the outpatient measures in such a tight timeframe.

Hospitals support expanding the quality information available to the public and reporting on standardized outpatient quality measures. It is essential, however, to ensure that the information reported is valid and reliable. We would question the validity and reliability of any data that is reported before the measures are fully field-tested. Additionally, expecting hospitals to implement in less than four months a new program that is tied to payment is unduly burdensome. Therefore, we urge CMS to delay data collection on the outpatient measures until the measures have been fully field-tested and received NQF endorsement, the data specifications have been finalized and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in 2008 when hospitals and vendors are fully prepared to commence the program.

Administrative Requirements of the Reporting Program

In the proposed rule, CMS outlines the administrative steps that hospitals must take to participate in the outpatient quality reporting program. The rule notes that hospitals must complete and submit a notice of participation form by November 15. We anticipate that there may be some confusion in the field around this requirement as hospitals were required to submit a similar form for participation in the inpatient quality reporting program in August. We urge CMS to communicate this requirement clearly and frequently to hospitals this fall and to work with its HQA partners so that all hospitals are aware of the steps they need to take to participate in the outpatient reporting program. We appreciate CMS' proposal that once a hospital has submitted a notice of participation, it will be considered an active participant of the program until the hospital indicates otherwise. This step will alleviate some of the administrative burden on hospitals, and we encourage CMS to adopt this policy in the final rule.

Data Submission Timeframe

The proposed data submission timeframe for the outpatient reporting program is 120 days, slightly shorter than the 135-day timeframe for the inpatient reporting program. If CMS chooses to adopt this shorter timeframe, the agency must be able to assure hospitals that updated data collection software will be available on the first day of the data submission period and that the necessary programming to receive the data at the data warehouse will have been completed and tested. Previously, delays in the availability of useable software for the inpatient reporting program have caused data submission delays for hospitals. Unless these recurring software problems can be resolved, CMS cannot shorten the timeline.

Data Validation

CMS is proposing data validation requirements for the outpatient quality reporting program. For 2009, CMS proposes randomly selecting for reabstraction five patient charts from each hospital from among those patients receiving services in January 2008. To pass validation, hospitals must meet a minimum of 80 percent reliability from the chart reabstraction.

The AHA opposes this proposal. Although hospitals have been collecting data for inpatient measures for several years, collecting data for the outpatient measures will involve the use of a new data collection tool with documentation criteria and forms that are different than the inpatient reporting program. The data likely will be collected by different staff. As with the implementation of any new program, there will be a learning curve as hospitals gain experience with the new program. Likewise, those staff members of the clinical data abstraction center with responsibility for the data reabstraction for validation will experience the same learning curve.

When the inpatient reporting program began, reabstraction and validation were used as learning tools for hospitals to improve their documentation and data collection. There was no minimum validation threshold determining whether or not hospitals received their full annual payment update. As the program evolved and hospitals gained experience with it, a minimum validation threshold was introduced and gradually raised to the 80 percent reliability rate. This was a thoughtful and deliberate approach to ensuring high reliability in the data used for the inpatient reporting program. **We urge CMS to undertake a similar approach for the outpatient program. For example, in 2009, data validation could be conducted as a learning tool for hospitals, but there should be no minimum reliability threshold required for the annual payment update. In subsequent years, a reliability threshold could be established at a lower level and then gradually raised to 80 percent.**

Reconsideration Process

For those hospitals that fail to meet the program requirements, CMS is proposing to implement a reconsideration process, similar to the one used for the inpatient reporting program. We believe that such a process is an essential component of the outpatient reporting program. CMS should establish a reconsideration process that is straightforward, transparent and timely.

ASCs: Quality Data

The Tax Relief and Health Care Act of 2006 mandated that the Secretary include ambulatory surgical centers (ASCs) in the outpatient quality reporting program. In the proposed rule, CMS delays implementing a quality reporting program for ASCs. The AHA encourages CMS to implement a quality reporting system for ASCs as soon as possible. All providers that perform the same services should be held to the same accountability standards with respect to the quality of the care they deliver.

OPPS: Partial Hospitalization

For the past two years, CMS has expressed concern that the median per diem cost derived from hospital and community mental health center (CMHC) claims data was too low to cover the cost of partial hospitalization programs (PHP) that typically span five to six hours per day. However, CMS still implemented a 15 percent decrease in the per diem for CY 2006 and then another 5 percent decrease in CY 2007. For CY 2008, CMS proposes another 24 percent drop in payments.

Cost-to-charge Ratios
For 2008, CMS proposes to adopt changes to its methodology for calculating PHP median costs using both hospital-based and CMHC PHP data. To more accurately estimate costs for PHP claims, CMS proposes to re-map 10 revenue center codes to a Primary Cost Center 3550, "Psychiatric/Psychological Services" or to a Secondary Cost Center 6000, "Clinic." In establishing the PHP median per diem rate, CMS proposes to calculate a separate per-diem cost for each day, rather than for each bill. **The AHA recommends that CMS conduct a similar analysis for CMHCs as PHP services are the highest-cost services they provide and may have statistically different cost-to-charge ratios than the overall CMHC cost-to-charge ratios.**

Median Costs
CMS analyzed the number of services being provided in a day of care as a possible explanation for the low per diem cost for PHP. It found that, despite its expectation that five or six services would be provided in a day, both hospital-based and CMHC PHPs have a significant number of days where three or fewer units of service were provided. Specifically, 34 percent of hospital-based PHP days contained three or fewer units of service, and 64 percent of CMHC PHP days contained three or fewer units of service.

CMS believes that its analysis of the number of units of service per day supports a lower per diem cost and thus, proposes to calculate the median per diem cost using all days, not just those with four or more units of service provided. Therefore, CMS proposes a per diem payment cost for 2008 of $178, which is 24 percent lower than the per diem cost of $233.37 for 2007.

CMS says that it did not propose separate rates for half-days and full-days because it believes the program was intended to cover a full day of service and that it was appropriate to set one rate that would be paid for all PHP days. The AHA, however, believes that there are circumstances that warrant less than a full day of services. For instance, when patients are transitioning out of the program or when there are other complicating physical ailments that require separate therapy. In addition, the partial hospitalization programs have evolved as the use of psychotropic drugs has increased and diminished the need for as much therapy. Even though a full day of services is not provided, such services are still valuable, necessary and warrant payment.

There is precedence for differentiating payments based on higher or lower utilization of services. For instance, under the home health PPS there is a low-utilization payment adjustment. Low-utilization payment adjustments are 60-day episodes with four or fewer visits where payment is based on a per visit basis. Following a similar pattern, CMS could set the PHP median per diem cost based on days when four or more services are provided and then pay a low-utilization payment adjustment amount for days when three or fewer services are provided. This approach would more accurately reflect resource intensity and ensure that those hospitals that provide more services per day are adequately paid. CMS could also put constraints around how frequently three or fewer services could be billed to prevent the bulk of days furnished by a provider being low utilization. We urge CMS to further research the possibility of such a payment structure for CY 2009.

The vast majority of patient days in hospital-based units are high-intensity services that may avoid a hospital stay, or a continued hospital stay. If additional hospitals reduce or eliminate PHP services, there will be increased demand for inpatient psychiatric beds that are already in short supply and, likely, additional bottlenecks in the emergency departments.

The AHA recommends that CMS maintain the CY 2007 rate of $233 to ensure continued beneficiary access to PHP services and further study the possibility of differentiating payment based on the intensity of services provided during a day of PHP services for CY 2009.

NECESSARY PROVIDER CAHS

CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). CMS believes that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

It is unclear in the rule to which provider-based entities CMS intends to apply this proposal. The provider-based regulations state that such determinations are not necessary for ambulatory surgery centers; comprehensive outpatient rehabilitation facilities; home health agencies; skilled nursing facilities; hospices; inpatient rehabilitation units; independent testing facilities; facilities, other than as parts of CAHs furnishing solely physical, occupational or speech therapy; ESRD facilities; ambulance providers; and rural health clinics (RHCs) with more than 50 beds. Thus, it is assumed that the proposal does not apply to these types of providers. It appears as if CMS intends the proposal to apply to psychiatric or rehabilitation distinct part units (even though rehabilitation units are on the list for which provider-based determinations are not necessary). It is unclear if CMS intended to include RHCs and outpatient departments. CMS should clearly state to which types of entities this policy applies.

Further, CMS’ proposal will have detrimental effects on all CAHs, not just necessary provider CAHs. Two CAHs could be 40 miles apart, but their provider-based entities could be within 20 miles of the other hospital in a town midway in between the CAHs. This rule would prevent either hospital from serving this town through a provider-based entity.

The AHA is unsure of CMS' motivation in making this proposal. There is nothing in the law to suggest that such an action is necessary. Nor, have we seen any recent direction from Congress to apply the mileage requirements, intended for the CAH itself, to its other lines of business. CMS is creating more burden for CAHs and potentially restricting access to care.

While there are payment advantages to CAHs under the inpatient and outpatient PPSs, there are no advantages for psychiatric and rehabilitation units. While the per visit limit for CAH-owned provider-based RHCs is waived, that is not unique to CAHs and is the case for any hospital with fewer than 50 beds. The location of provider-based entities nearer to the next hospital than the CAH itself does not pose an unfair market advantage compared to neighboring hospitals. Surrounding PPS hospitals are able to locate their provider-based entities wherever they chose as long as they continue to meet the provider-based criteria. Thus, if anything, this policy would put CAHs at a distinct disadvantage compared to their local PPS counterparts.

If CMS implements this policy, it may have broader effects on community access to care than the agency anticipates. CAH provider-based entities are located in different places for various reasons often unrelated to where the next hospital is located. Hospitals consider available land, natural boundaries, increased need, preference of physicians and other practitioners, etc. While community members may be willing to travel a distance to a hospital for urgent/emergent care or services not available elsewhere, beneficiaries want something closer to home for more routine visits, therapy, lab work, etc. By forcing the CAHs to have all services on-campus, CMS will be creating geographical bare patches that leave some communities members without access to services.

Additionally, clinics and distinct part units are often a way CAHs recruit physicians to practice in the area. By hiring a physician at one of the CAH's provider-based entities, the CAH guarantees that there is a physician in the area to serve on the medical staff. There are small communities nationwide within 35 miles of a CAH that would have no physician without a RHC. As older physicians retire or younger physicians relocate, the ability to set up a RHC would be critical to the continuation of basic medical care in rural areas. The hospitals that are affected by this rule are small and rural by their nature and all of them already have trouble recruiting and retaining physicians. CMS should not make it more difficult for CAHs to recruit and retain needed personnel.

Finally, the "grandfather" provision that extends only to provider-based entities that maintain the same location will inappropriately lock them into outdated facilities. Some CAHs are operating provider-based entities in very old buildings that need to be replaced, which often means relocation. Many hospitals are in the middle of planning or actively constructing new facilities. The financial viability of these projects revolves around provider-based status. Officially changing this requirement November 1 for January 1 implementation is simply not reasonable or feasible.

CMS should rescind this proposal. It is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Moreover, CMS' policy

would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

REPLACED DEVICES

In the 2007 OPPS final rule, CMS adopted a policy that reduces the APC payment to a hospital or ASC for selected device-dependent APCs when the hospital receives certain replacement devices without cost or receives a full credit for the device being replaced. The CY 2007 reduction policy does not apply to cases in which there is a partial credit toward the replacement of the device. For 2008, CMS proposes to expand the policy to require hospitals to report occurrences of devices being replaced under warranty or otherwise with a partial credit granted to the hospital so that the agency can identify systematic failures of devices or device problems through claims analysis and make appropriate payment adjustments.

CMS proposes to create a HCPCS modifier that would be reported in all cases in which the hospital receives a partial credit toward the replacement of one of the 31 medical devices listed in Table 39 of the proposed rule. CMS proposes to reduce the payment for the APC into which the device cost is packaged by one half of the amount of the offset amount that would apply if the device were being replaced without cost or with full credit when the amount of the device credit is at least 20 percent of the cost of the new replacement device being implanted.

Under the analogous policy adopted in the 2008 final inpatient rule, CMS only applies the reduced payment to cases in which the hospital receives a credit equal to 50 percent or more of the cost of the device. This ensures that the reduction in payment does not occur when the credit is nominal or relatively inconsequential in comparison to the overall payment for the case. **CMS should raise the proposed threshold from 20 percent to 50 percent in the final OPPS rule, as is the case under the inpatient PPS.**

We concur with CMS that requiring hospitals to reduce their charges in proportion to the partial credit or to provide paper invoices or other information to the fiscal intermediary (or Medicare administrative contractor) indicating the hospital's normal cost of the device and the amount of the credit received would impose an unacceptable administrative burden on hospitals. We urge CMS to exclude any such requirements in the final rule.

The AHA also is concerned about proper billing and the potential for payment delays that could occur while a returned device is being evaluated during a warranty service period. Hospitals frequently do not know whether a manufacturer will agree that a returned device is covered under the warranty or the amount of credit that will be granted. In the 2008 final inpatient rule, CMS acknowledged the validity of similar concerns and agreed that hospitals should have the options of either: 1) submitting the claims immediately without the special condition code (Condition Code 49 under the inpatient PPS) and then submitting a claim adjustment with the condition code at a later date once the credit determination is made, or 2) holding the claim until a determination is made on the level of the credit. We believe that CMS should give hospitals the same options for reporting the HCPCS modifier under the OPPS.

OPPS: Hospital Visits

Since April 2000, hospitals have been using the American Medical Association's (AMA) Current Procedural Terminology (CPT) evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors – designed to reflect the activities of physicians – did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

In 2003, the AHA and the American Health Information Management Association (AHIMA) recommended hospital E/M visit guidelines based on the work of an independent expert panel comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience.

Despite CMS' previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 the agency established new HCPCS level II G codes to distinguish visits provided by Type B EDs (not open 24 hours a day, seven days a week – 24/7).

Proposed Codes and Coding Policy for 2008

For 2008, CMS proposes to continue using CPT E/M codes for clinic visits including separate codes for new and established patients. The agency also proposes to cease paying for consultation E/M codes under OPPS and instead to instruct hospitals to bill a new or established visit code. Differentiating hospital visit codes between new and established patients, or between standard visits and consultations, adds an unnecessary level of complexity and is difficult to implement. **We support CMS' proposal to eliminate the consultation codes, but urge CMS not to implement the codes for new and established patient clinic visits.**

While current distinctions in the physician E/M codes exist, the same concepts do not apply to facility resources. From a physician's perspective, an established patient may require a shorter history and a less comprehensive physical exam. These same economies are not necessarily factors in determining facility resource codes. For example, a person may be an established patient to a facility because of previous visits to any number of outpatient settings, including the ED, a clinic, as an inpatient, for a diagnostic exam or for any other service. Previous services may or may not be related to the current visit, but it would be extremely burdensome for facilities to have to determine whether there was a previous encounter and whether previous services performed are related to the current visit. This determination is especially difficult for medium-sized hospitals and nearly impossible for small hospitals. For these hospitals, rural communities in particular, nearly every patient ever seen will have had some type of contact with the hospital.

The interventions performed during an encounter are determined by physician orders, but the actual performance of these interventions would be the same whether the patient was new or established. Current distinctions on new vs. established patients for hospital coding are based on whether the patient has a medical record number within the previous three years. **We believe that the clinic visits should be recognized on the basis of hospital resources utilized during a specific visit, and therefore, not determined by whether the patient has been seen by the hospital within the last three years. CMS should withdraw this proposal.**

<u>ED Visits</u>. We continue to be concerned about CMS' payment structure for Type A and B ED visits. Specifically, the new policy implemented by CMS' 2007 final OPPS rule led to significant confusion and concern about how hospital "fast tracks" are treated. Fast tracks generally function as a part of the ED that handles specialized cases (e.g. heart-related emergencies) or less emergent cases so that patient flow can be improved through a hospital ED. They can be physically adjacent or even located within the 24/7 ED but, hospitals often discontinue triaging patients to fast tracks during certain hours (e.g., the midnight shift).

Paying non-24/7 ED fast tracks at the clinic rate does not make sense from a national policy perspective. ED overcrowding and ambulance diversions are significant issues for America's health care system and fast tracks improve patient care, patient flow and patient satisfaction. CMS' policy has led many hospitals to consider closing these special units, a move that would exacerbate the nation's ED diversion and overcrowding problems.

The AHA believes CMS' policy can be improved to be clearer on the appropriate coding for fast track ED services. We recommend applying the following criteria.

If a hospital with a Type A 24/7 emergency department has a "fast track" area to which some patients are sent for expedited or specialized care, the fast track area is part of the Type A ED and can bill using the Type A ED CPT codes, regardless of the fast track's hours of operation, as long as:

- **the fast track is a hospital-based facility which provides unscheduled episodic services to patients who present for immediate medical attention;**
- **the fast track area is physically located within the same building as the 24/7 ED; and**
- **the 24/7 ED and the fast track share a common patient registration system.**

<u>ED Critical Care Visits</u>. For 2007, CMS reaffirmed the criteria for payment for critical care services to require a minimum of 30 minutes of critical care services provided. From a facility perspective, a patient requiring at least 30 minutes of critical care would typically be admitted as an inpatient.

We recommend that the criteria for payment for critical care services be changed to a minimum of 15 minutes of critical care or the patient expires in spite of the administration of critical care services. Very significant hospital resources are utilized in the delivery of critical care services, including multiple hospital staff members. These services are not appropriately recognized if the patient expires or is transferred before the completion of 30 minutes of service.

Proposed Treatment of Guidelines for 2008
CMS is not proposing to implement national visit guidelines for clinic or ED visits for CY 2008. In the proposed rule, CMS reiterated the set of principles it expects hospitals' internal guidelines should follow and requested comments on five additional principles.

The AHA is concerned that CMS is uninterested in developing or approving national guidelines for the reporting of hospital ED or clinic visits. Since the implementation of OPPS, the AHA has advocated for the development of national guidelines and unique codes to represent facility resources, rather than physician resources, used in the delivery of clinic and ED visits. CMS has poor data to calculate crucial APC reimbursement since there is no standard definition or standard application of E/M codes. Since hospitals are using different methodologies, (time, interventions, patient complexity or severity, etc.), each hospital's reported E/M levels reflect a different aspect of hospital resource utilization.

In the CY 2007 OPPS final rule, CMS indicated that "most commenters strongly supported creation of national guidelines." We are, therefore puzzled as to why CMS requested public comment as to whether there was still a pressing need for national guidelines. **The AHA continues to believe in the need for national guidelines for hospital ED and clinic visits.** The same reasons identified in previous comments from the AHA, as well as other providers, since 2001 regarding the need for national guidelines remain valid. In order to "play by the rules" a clear and detailed set of rules are needed. In the August 9, 2002 OPPS proposed rule, a summary of the comments received by CMS regarding the need for national guidelines included the following reasons:

- Facilities need to comply with HIPAA requirements (concern that use of E/M codes with different reporting rules and meanings when used by facilities would violate HIPAA requirements for using the standard code sets)
- To set up effective audit and compliance programs
- To minimize confusion on the part of coders
- To minimize inaccurate payments
- To prevent gaming of the system

The AHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA CPT Editorial Panel to create CPT codes for hospital visits. These codes then could be widely reported by hospitals to all payers.

While the set of principles that hospitals' internal coding guidelines are expected to follow may appear lofty and praiseworthy, in reality, they are worrisome because of the lack of specificity and definitions. We believe that if hospital guidelines are to be judged by these principles, it would be extremely difficult to satisfy these principles without additional guidance. The following issues and questions arise:

- How can guidelines follow the intent of the CPT code descriptors when the CPT E/M codes reflect intensity of resources that are not relevant factors in hospitals? For example, CPT E/M codes consider the history, physical examination and medical decision-making as the variable for determining physician resources. What would CMS consider appropriate variables to account for hospital resources in determining ED or clinic visits? Based on previous examples of hospital visit models submitted, some consider nursing interventions, time, diagnoses or complaints, patient acuity, or a combination of these.
- Principles such as "guidelines should be clear to facilitate accurate payments and be usable for compliance purposes and audits" are subjective and open to interpretation. A guideline may be clear to a coding professional but confusing to an auditor.
- Without national guidelines and unique codes and accompanying descriptors for hospital ED and clinic visits, guidelines cannot meet the HIPAA requirements. These requirements necessitate using codes based on the descriptors and definitions developed by the code set maintainer – the hospital. Current CPT codes describe physician services.
- What is the definition of great frequency? It is difficult for providers to meet a principle stating that guidelines should not change with great frequency when the definitions and concepts as to what may or not be specifically included in a clinic or ED visit code have changed since OPPS implementation. For example, hospitals may have had to redefine their ED visits or create new guidelines on the basis of last year's distinction between Type A and Type B ED visits. Another example is whether separately payable interventions may be included in the determination of a level. Initially, CMS was silent on this topic, but in 2002 commented that separately payable interventions should not be included. The list of packaged HCPCS codes can change annually, thereby necessitating their removal from the interventions included in the guideline. For example, bladder catheterization services were formerly packaged and then changed to being separately payable under certain circumstances.
- What is the definition of "readily available" in the principle regarding guidelines being readily available for fiscal intermediaries or Medicare administrative contractors? How should these guidelines be available?
- How will it be determined whether guidelines result in coding decisions that could be verified by other hospital staff as well as outside sources? Even with national standards and national definitions (such as with ICD-9-CM), there can sometimes be room for interpretation among coders and with outside sources requiring additional clarification and education.

<u>Inclusion of Separately Payable Services in Visit Levels</u>. In the CY 2007 proposed OPPS rule, CMS indicated that it was open to further discussion and welcomed public comments on the exclusion of separately payable services from the national visit guidelines. In the CY 2007 final OPPS rule, CMS agreed with commenters that there may be advantages to including separately payable interventions in the guidelines as examples because a measure of acuity may be lost in the absence of recognition of these procedures. In the absence of national guidelines, we urge CMS to clarify whether separately payable procedures may now be included in hospital-specific guidelines.