August 29, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS–1525–P, Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements; (Vol. 76, No.137), July 18, 2011.

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) calendar year (CY) 2012 hospital outpatient prospective payment system (OPPS), ambulatory surgical center (ASC), physician self-referral proposed rule. The AHA will submit comments separately on CMS’s proposed changes to the hospital value-based purchasing program.

We provide detailed comments on several proposals in the attached document. The AHA has concerns and comments about CMS’s proposed process for the independent review of alternate supervision levels, the methodology for calculating the cancer hospital adjustment, the wage index options for which CMS is soliciting comments, the payment rates for separately payable drugs, requirements for outpatient quality data reporting, hospital visit coding guidelines, critical care payment policy, partial hospitalization program (PHP) services payment policy, quality reporting through the electronic health record (EHR), physician self-referral changes and changes to the physician availability patient notice. In brief, the AHA makes the following key recommendations:

- While the AHA supports the establishment of an independent review process that would allow for an assessment of the appropriate supervision levels for individual hospital
outpatient therapeutic services, we remain concerned that several aspects of CMS’s proposal are inconsistent with the approach that the AHA has recommended in previous comments.

- The AHA strongly supports CMS’s decision to provide an additional year of delayed enforcement for critical access hospitals (CAHs) and small rural hospitals.
- We are disappointed that in the proposed rule, CMS retains its overall requirement that outpatient therapeutic services remain subject to a default standard of direct supervision.
- Clinical evidence and documentation that demonstrate that there is a need for personal supervision should be provided before CMS embarks on a committee process involving assigning a level of supervision above direct supervision for outpatient therapeutic services.
- The AHA supports the CMS proposal to add several CAH representatives to the federal Advisory Panel on Ambulatory Payment Classification Groups (APC Panel). We further recommend that representatives from small rural (PPS) hospitals also be added.
- The AHA opposes CMS’s proposal to use a sub-regulatory process in making a final decision on revising the level of supervision for outpatient therapeutic services. Instead CMS’s decisions about APC Panel recommendations should be subject to notice and comment through a public rulemaking process.
- The AHA continues to disagree with CMS’s repeated assertion that it has required direct supervision for all outpatient therapeutic services, regardless of whether they are furnished in the hospital, on its main campus or in an off-campus provider-based department, since 2001.

- We recommend that CMS revise its proposed methodology for calculating the cancer hospital adjustment to include cancer hospitals' expected transitional outpatient payments (TOPs).
- While the AHA prefers not to perpetuate the currently flawed wage index system, we are unable to evaluate and take positions on the modifications for which CMS solicits comments due to the lack of detail provided. We urge the agency to provide more details on its options in the final rule.
- The AHA recommends that CMS abandon, due to its instability, its current methodology for calculating the payment rate for separately covered outpatient drugs. Instead, CMS should pay for the acquisition cost of separately covered outpatient drugs at the rate at which they are paid in physician offices, currently average sales price (ASP) plus 6 percent, as permitted by law.
- Among the detailed comments we include on each of the ten proposed measures, we urge CMS to use only measures endorsed by the National Quality Forum (NQF).
• Given CMS’s apparent lack of interest in adopting national visit coding guidelines, the AHA urges CMS to partner with the AHA to request that the American Medical Association’s (AMA) Current Procedural Terminology (CPT) Editorial Panel create unique CPT codes for hospital reporting of emergency department (ED) and clinic visits based on hospitals’ internally developed guidelines.

• In order to ensure continued beneficiary access to hospital-based PHP services, particularly in rural areas, we recommend that CMS set the payment rates for CY 2012 at the CY 2011 rate. This will help stabilize access to these critical services and give CMS sufficient time to evaluate what is driving the drop in median costs, assess the implications for access to care and determine whether any changes, legislative or regulatory, need to be made to the PHP.

• While the AHA supports the concept of beginning the ASC Quality Reporting Program, we are concerned that CMS is proposing measures that have not been tested for use in ASCs.

• The AHA continues to urge CMS to require ASCs to begin to routinely report cost data to allow for future validation of the relative appropriateness of ASC payment weights and rates.

• While the AHA supports the concept of the proposed electronic quality reporting pilot, we have significant concerns about the proposal presented. We recommend a different kind of pilot be conducted that focuses on whether electronic health records (EHRs) can accurately generate quality measure data that are valid, reliable and comparable across hospitals.

• The AHA agrees with and supports the overall approach taken by CMS regarding the exceptions to the ban on growth by grandfathered existing physician-owned hospitals.

• The AHA supports CMS’s decision to roll back provision of the physician availability notification for outpatients except when the services furnished involve observation, surgery, or any other procedure requiring anesthesia.

Thank you again for the opportunity to comment. Our detailed comments are attached. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

Attachments
PROCESS FOR INDEPENDENT REVIEW OF ALTERNATE SUPERVISION LEVELS

In the CY 2012 proposed rule, CMS follows through on its plan described in the CY 2011 final rule to establish an independent review process that would allow for an assessment of the appropriate supervision levels for individual hospital outpatient therapeutic services. In general, the AHA supports the establishment of such a process. In previous comments to CMS, we urged the agency to adopt a more comprehensive and clinically-based approach for assigning levels of physician supervision to outpatient therapeutic services and requested that the agency change its supervision policy. Such fundamental changes fall clearly within the authority of CMS. That is, while Medicare covers hospital outpatient therapeutic services as “incident to” a physician’s service, the law does not mandate a specific level of physician supervision, but rather leaves this entirely within CMS’s regulatory discretion. We believe that there are numerous outpatient therapeutic services covered by Medicare that could be provided safely under general supervision, including certain extended duration services, short duration services, minor surgical procedures and the recovery portion of certain surgical services. In addition, the AHA continues to disagree with CMS’s repeated assertion that in the 2009 final rule, the agency was merely restating and clarifying its existing direct supervision policy dating back to 2000, and we strenuously object to the application of this policy to outpatient therapeutic services furnished since 2001.

The AHA is very concerned with several aspects of CMS’s current proposal for the independent review process that could impede hospitals’ ability to continue to provide certain outpatient therapeutic services. First, we are disappointed that in the proposed rule, CMS retained its overall requirement that outpatient therapeutic services remain subject to a default standard of direct supervision. By contrast, under the AHA’s approach, CMS would have adopted a default standard of general supervision for outpatient therapeutic services, with an exceptions process established to identify specific procedures that should be subject to direct supervision. We contend that general supervision better reflects the way in which on-campus outpatient therapeutic services were furnished prior to 2009, particularly in rural hospitals, and there is no evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision.

In addition, the AHA urges CMS to provide clinical evidence and documentation that demonstrates that there is a need for personal supervision. The AHA does not see the need to introduce the concept of personal supervision for outpatient therapeutic services. All hospital outpatient therapeutic services are provided with the highest quality of care principles in mind. The provision of care is governed by clinical protocols, policies and procedures that are based on clinical evidence and are approved by the hospital’s medical staff. Those therapeutic services that are too complex and/or risky to perform in an outpatient setting are already done on an inpatient basis. CMS formalized this notion through the creation and maintenance of its inpatient list. Further, the higher risk and more complex services that are covered by Medicare in outpatient settings, such as certain surgeries and other invasive therapeutic procedures, are already directly performed by a physician, thus obviating the need for supervision altogether.

Other services furnished in the hospital outpatient department that are not directly performed by
a physician or non-physician practitioner (NPP) are furnished by other licensed, skilled professionals under the supervision of a physician or an NPP. For more than 10 years, hospitals and critical access hospitals (CAHs), both rural and urban, have successfully ensured access to high-quality outpatient therapeutic services utilizing general and direct supervision. In short, there is simply no evidence of safety or quality of care problems to support the need for CMS to assign outpatient therapeutic services to a level of “personal supervision” by a physician.

The AHA also has comments and concerns about the specifics in CMS’s proposed rule regarding the selection of the review body, the review process, and the evaluation criteria, as described below.

**Selection of the APC Panel to Review Supervision Levels.** CMS proposes to establish the APC Panel as the independent review body that will be reviewing individual services for possible reassignment of their supervision level. Consistent with the AHA’s recommendations, CMS proposes to amend the APC Panel charter to reflect this new role and would add two to four new CAH representatives as panel members. **The AHA supports CMS’s proposal to add CAH representatives to the panel. However, we believe that to ensure a strong voice for small and rural hospitals, four CAH representatives should be added, rather than two or three. In addition, as other, non-CAH rural hospitals also are having great difficulty in complying with the direct supervision requirements, the AHA recommends that CMS add four representatives from small rural PPS hospitals to the panel.** While adding a total of eight CAH and small rural hospital representatives to an existing APC Panel comprising representatives of 15 hospitals that are neither small nor rural will not guarantee an equal voice for rural concerns and issues, it will certainly help to lay the groundwork for a more balanced discussion of supervision issues.

The agency proposes to create a new supervision subcommittee that is charged with evaluating appropriate supervision standards for individual services and presenting its deliberations to the full APC Panel. Each member of the full APC Panel would then vote on the recommendations to CMS. Because CAHs are not paid under the OPPS, CMS proposes that while CAH representatives would be permitted to vote on APC Panel recommendations that involve supervision requirements, they would be excluded from voting on recommendations involving OPPS payment policy. **The AHA recommends that if small rural PPS hospital representatives are appointed to the APC Panel, they should not only participate in the new supervision subcommittee but also be permitted to vote on APC Panel recommendations that involve other OPPS payment policy.**

**Review Process.** CMS proposes to diverge from its standard practice in making decisions based on APC Panel recommendations. That is, CMS proposes not to subject its decisions on APC Panel recommendations regarding supervision levels to formal public notice-and-comment rulemaking. Rather, CMS would use a sub-regulatory process in which its decisions would be posted on the OPPS website for informal public review and comment, and decisions would be effective either in July or January following the most recent APC Panel meeting.
The AHA opposes CMS’s proposal to use a sub-regulatory process in making a final decision on revising the level of supervision for outpatient therapeutic services. In order to ensure full and appropriate consideration by stakeholders, CMS’s decisions about the APC Panel’s recommendations should be subject to notice and comment through a public rulemaking process.

CMS states that a sub-regulatory process would best serve the interests of beneficiaries and other stakeholders because changes in supervision levels could be made more often and more quickly than through annual OPPS rulemaking. However, as CMS has demonstrated repeatedly over the last several years, regulatory changes can be made in a payment system through unrelated rulemaking. For instance, the CY 2012 OPPS proposed rule contains a number of non-OPPS changes. Alternatively, CMS has the option of issuing interim final rules or final rules with comment period to allow the public to weigh in on changes that occur after a proposed rule has been issued. This is the approach that CMS currently uses to assign certain new Current Procedural Terminology (CPT) codes to APCs. Further, as the APC Panel meets only twice a year, CMS would need to find just one additional proposed rule in which to issue its proposed decisions on APC Panel recommendations for public comment. Additionally, CMS’s concern about the ability to make swift changes to address problems associated with supervision is overstated. CMS already has multiple mechanisms to rapidly alter its policies if patient access or quality of care is at stake. For instance, it can use its enforcement discretion or delayed implementation of a policy. Using formal rulemaking also has the advantages of greater transparency and more concrete assurance that feedback from interested stakeholders will be given serious consideration by CMS.

**Evaluation Criteria.** CMS proposes that requests for the APC Panel to revise the supervision level for specific services would be submitted through the panel’s standard process and CMS could also independently request review of specific services. If CMS receives an unmanageable number of requests, the agency proposes to prioritize requests by service volume, total expenditures and/or frequency of requests. CMS would require that requests include justification for the change in supervision level that is sought, supported, to the extent possible, with clinical evidence.

The AHA supports CMS’s proposed processes to ensure that the services selected for review by the APC Panel represent those that are the highest priority in terms of volume, cost and public concern. We also recommend that services that are high volume/priority in CAHs and small rural PPS hospitals be considered as high priority if they differ from larger hospitals.

CMS proposes to charge the APC Panel with recommending a supervision level to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a CPT code. The APC Panel would be instructed to consider the clinical, payment and quality context of a patient encounter, the likelihood that a patient’s care would need to be reassessed or modified by a supervisory practitioner during the therapeutic intervention and whether guidance or advice to the hospital staff furnishing the services would be needed. In addressing these issues, the APC
Panel would be directed to consider the service’s complexity, the acuity of patients receiving the services, the probability of an unexpected or adverse patient event occurring and the expectation of rapid clinical changes during the service or procedure.

The AHA generally supports the clinical review criteria that CMS describes as appropriate. However, we believe that CMS also should explicitly include among these criteria the consideration of the varied environments in which the services to be evaluated are furnished to Medicare beneficiaries. In particular, consideration should be given to whether the service is commonly furnished in small rural hospitals and CAHs and the particular challenges the hospitals face in ensuring access to primary care and specialty outpatient therapeutic services in an environment of severe shortages of physicians and NPPs.

Other Considerations. There are several other recommendations that the AHA originally made in its comments about the CY 2011 OPPS final rule that bear repeating for CY 2012:

- CMS and its contractors should not be permitted to use for enforcement purposes the information presented by providers who are requesting consideration by the APC Panel of a reduced level of supervision for certain services.

- As a starting point, CMS should prepare for the APC Panel’s consideration a subset of Medicare covered outpatient therapeutic services that are paid under both the OPPS and the physician fee schedule, and for which the physician fee schedule assigns a physician relative work value of less than 1.0. Due to the low physician work involvement inherent in these services, they are more likely to be the types of services for which general supervision would be justified. In the AHA’s analysis of these services, we found that most of the services that CMS included in the CY 2011 set of 16 “nonsurgical extended duration therapeutic services” fall into this category. We continue to believe that these services should be considered for general supervision.

- The APC Panel should be permitted to consider certain surgical services, as well as some portion of the recovery period of certain surgical services, for a reduced level of supervision. We continue to believe that there are low-risk, minor surgical procedures that could be performed safely under general supervision in a hospital outpatient department. Further, we believe that for many types of surgeries, there is a point during the recovery period, perhaps after the patient has been cleared by the anesthesiologist, when it is safe for the level of supervision to transition from direct to general.

Further Delay of Enforcement for CAHs and Small Rural Hospitals. CMS estimates that policy decisions on many key services would not be completed until sometime in 2012. In the interim period, the agency proposes to extend for an additional year – through CY 2012 – its decision not to enforce the direct supervision policy for outpatient therapeutic services provided in CAHs and small rural hospitals with 100 or fewer beds. The AHA strongly supports CMS’s decision to provide an additional year of delayed enforcement for these hospitals.
Conditions of Payment for Hospital Outpatient Therapeutic Services Described by Different Benefit Categories. CMS proposes to revise the regulations to clarify that therapeutic services and supplies that are covered by Medicare through a Social Security Act statutory benefit category other than “incident to” services are nevertheless subject to the supervision and other regulatory requirements under 42 CFR 410.27 when they are furnished to hospital or CAH outpatients. CMS states that this is intended to answer questions that have been raised regarding whether hospitals are required to comply with supervision requirements when they furnish services, such as radiation therapy, that have a separate statutory benefit category.

The AHA requests that CMS clarify more explicitly in the final rule that this revision is intended to apply only to those hospital outpatient therapeutic services and supplies that are paid under the OPPS and to CAHs and would not apply to those services furnished in hospital outpatient departments but that are paid under different Medicare payment systems, such as the physician fee schedule and the clinical laboratory fee schedule.

Cancer Hospital Adjustment

There are 11 cancer hospitals in the United States that, while they are paid under the OPPS, are accorded under law a permanent payment floor, commonly referred to as a “hold harmless” payment, that limits their potential losses under the OPPS. That is, these cancer hospitals receive transitional outpatient payments (TOPs) that ensure they are not paid less under the OPPS than the payment they would have received before implementation of the OPPS. The TOPs are not required to be budget neutral. The OPPS also has a provision for temporary “hold harmless” payments for small rural hospitals with 100 or fewer beds and for all sole community hospitals. While these temporary TOPs for small rural hospitals and SCHs are set to expire on December 31, 2011, cancer hospitals remain permanently eligible. The federal TOPs made to cancer hospitals are substantial, with the 11 cancer hospitals receiving about $158 million, over 60 percent of the total $258 million in TOPs, according to hospital cost report data.

Cancer Hospital Adjustment Required by ACA. Section 3138 of the Patient Protection and Affordable Care Act (ACA) requires CMS to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals with respect to APC groups, including the cost of drugs and biologicals, exceed the costs incurred by other hospitals furnishing services under the OPPS. If cancer hospitals’ costs are determined to be greater than the costs of other hospitals paid under the OPPS, CMS must provide for an “appropriate adjustment” to reflect these higher costs. The adjustment must be accomplished through the existing “equitable adjustment” authority in Section 1833(t)(2)(E) of the Social Security Act, which requires the adjustment to be budget neutral.

CMS conducted two analyses intended to evaluate the relative costliness of cancer hospitals compared to other hospitals and concluded that cancer hospitals are more costly than other hospitals paid under the OPPS because:
• cancer hospitals’ cost per discounted unit standardized for service mix is higher than the standardized cost per discounted unit of all other hospitals; and,
• cancer hospitals’ volume weighted average payment-to-cost ratio (PCR) is lower than the volume weighted PCR of other hospitals paid under the OPPS.

Based on these analyses, CMS proposes to increase each cancer hospital’s OPPS payment by the percentage difference between its individual PCR without TOPs (on average, 0.646) and the weighted average PCR of other hospitals paid under the OPPS (0.901). CMS estimates that this proposed adjustment would result in aggregate increases in OPPS payments to cancer hospitals of 39.3 percent for 2012. In order to meet the law’s requirements for budget neutrality, CMS proposes to reduce payment to all other hospitals by 0.6 percent, or $221 million. CMS proposed, but did not finalize, a similar adjustment in CY 2011.

**Impact of CMS’s Proposal.** CMS expects that as a result of this proposed adjustment, none of the 11 cancer hospitals will receive “hold harmless” TOPs in 2012. CMS chose not to consider TOPs – payments that cancer hospitals are guaranteed by law to receive on a permanent basis – in calculating the magnitude of its proposed cancer hospital “appropriate adjustment.” CMS’s proposal essentially eliminates its obligation for the “hold harmless” TOPs, estimated at $158 million, and shifts this financial burden to all other hospitals.

Further, as a result of the elimination of TOPs payments, the cancer hospitals’ net gain would be reduced to approximately $63 million. Therefore, while all other hospitals would bear the full weight of the budget neutrality reduction in payment of $221 million, only $63 million of that amount would directly benefit the cancer hospitals. The $158 million balance represents the shifting of the responsibility for what Congress intended to be permanent “hold harmless” payments from the federal government to other hospitals.

The adjustment that CMS proposes to make to cancer hospital APC payments would also result in a substantial increase in beneficiary out-of-pocket costs for services furnished in cancer hospitals. This occurs because the law requires that beneficiaries pay 20 percent of the Medicare APC payment rate, which results in seriously ill beneficiaries undergoing cancer treatment in these hospitals bearing an additional $44 million in copayments. While many beneficiaries purchase secondary insurance that would cover these additional copayments, those beneficiaries who cannot afford such coverage may find it difficult or impossible to pay and could even decline treatment. Cancer hospitals could also expect an increase in bad debt as a result of increased patient copayments.

In addition, the substantial increase in copayments for services in dedicated cancer hospitals could harm their ability to compete with other hospitals that also provide cancer care services, but with lower out-of-pocket costs for patients. This could cause dedicated cancer hospitals to lose patients to competing hospitals that also offer cancer care.

This impact on the ability of dedicated cancer hospitals to compete would not only harm these individual hospitals but could also interfere with progress in state-of-the-art treatments for
Unlike other hospitals that offer a variety of services to patients, these 11 dedicated cancer hospitals are singularly dedicated to deepening the understanding of the causes of and cures for cancer, developing new treatments for cancer and disseminating this knowledge to the provider community at large. Much of the recent progress in understanding cancer’s biology and effective treatment is directly attributable to their work. Impeding the ability of these facilities to compete for patients could also impede the progress in cancer care.

CMS’s proposal would also reduce outlier payment to cancer hospitals. Eligibility for Medicare outlier payments is determined by comparing a hospital’s cost for a service to the APC payment amount they receive. An APC amount that is significantly inflated by the cancer hospital adjustment would result in reduced eligibility for outliers as well as reduced outlier payments.

So while, on its surface, CMS’s proposal appears to provide a large benefit to cancer hospitals, the net benefit for these facilities is, in fact, much smaller when one considers the full impact of the proposal. The benefit of the adjustment is significantly reduced when one considers their disappearing “hold harmless” payments, reduced ability to compete with other hospitals in their primary line of business, declining outlier payments and increased bad debt. For Medicare beneficiaries suffering from cancer, the impact is increased out-of-pocket costs for the same services and potentially reduced access to care. CMS’s proposal could also pose a barrier to advances in cancer care treatment.

For all other hospitals, the proposal is more than unfair. Their payments are reduced by $221 million, but only 28 percent of that amount ($63 million) is transferred directly to the dedicated cancer hospitals. The only party that benefits outright from this proposal is the federal government, which received a windfall of $158 million in savings from the elimination of the “permanent” cancer hospital TOPs. It seems unlikely that this outcome is what Congress intended when it enacted Section 3138 of the ACA.

Incorporating TOPs in Calculation of Cancer Hospital Adjustment. The AHA supports an appropriate payment adjustment for cancer hospitals; however, we do not believe that CMS’s proposed cancer hospital adjustment is consistent with congressional intent, nor can it be considered “appropriate” due to its disregard of the significant federal TOPs payments that cancer hospitals are granted and the significantly negative financial impact it will have on all other hospitals. We once again urge CMS to consider TOPs in its methodology for calculating the magnitude of the cancer hospital adjustment.

Congress allowed CMS considerable flexibility in determining the type and magnitude of the cancer hospital adjustment. The ACA only requires that the adjustment be “appropriate…to reflect those higher costs” and be made in a budget-neutral manner. Clearly, Congress’s intent was to achieve greater payment equity among the cancer hospitals as compared to all other hospitals. The AHA believes that a reasonable examination of how to achieve payment equity must consider all of the payments that the cancer hospitals are already entitled to receive, both the APC payments for individual services as well as the TOPs payments. An “appropriate” cancer hospital adjustment should reflect a marginal increase beyond that amount.
Further, by requiring the cancer hospital adjustment to be implemented using the “equitable adjustment authority,” Congress explicitly required that it have a budget-neutral impact on federal outlays. This is evidenced not only by the explicit language contained in the ACA, but also in the related $0 federal budget impact that the Congressional Budget Office estimated for Section 3138 of the ACA. However, due to CMS’s proposed methodological approach, federal outlays, as a result of reduced TOPs, will actually decline significantly from the level that would have been paid in the absence of the cancer hospital adjustment.

CMS argues that it cannot consider TOPs in assessing costliness of cancer hospitals relative to other hospitals furnishing OPPS services because “section 3138 of the ACA requires that any cancer adjustment be made within the budget-neutral system” and “that TOPs are based on reasonable cost and are not part of the budget-neutral payment system.” The AHA disagrees with CMS’s statement that the ACA requires that the cancer hospital adjustment be made within the budget-neutral “system.” What the equitable adjustment authority requires is that adjustments be established in a “budget-neutral manner.” As we explained above, CMS’s proposed cancer hospital adjustment is not made in a budget-neutral manner; it actually reduces federal expenditures significantly by eliminating TOPs for all of the cancer hospitals receiving the adjustment. Moreover, the ACA does not require that, in determining the amount of the cancer hospital adjustment, CMS consider only those payments that exist within the budget-neutral “system.”

Therefore, the AHA once again strongly recommends that CMS consider the “hold harmless” TOPs payments in its determination of the level of the appropriate adjustment. One way to do this is to establish an adjustment that increases cancer hospital costs by an amount that is equivalent to the estimated difference between their individual OPPS PCR with TOPs (on average, 0.831) and the OPPS PCR for other hospitals (0.901). This approach would provide for both an appropriate increase in payments for cancer hospitals as well as a much smaller budget-neutral reduction in payment for other hospitals. This approach also would result in more of the cancer hospitals remaining eligible to receive TOPs for 2012 than would be the case under CMS’s proposal.

In the AHA’s comments to the CY 2011 OPPS proposed rule, we stated that cancer hospitals should not be penalized for receiving adjustments intended to improve payment equity and therefore recommended that CMS not include the cancer hospital adjustment amount in calculating these hospitals’ eligibility for TOPs or for calculating the amount of the TOPs. After reviewing and validating CMS’s analysis, we agree that, according to current law, the agency does not have the authority to exclude the cancer hospital adjustment amount from the TOPs calculation. That said, it is hard to believe that Congress truly intended that its provision to help cancer hospitals would result in the elimination of their “permanent” TOPs. Therefore, we urge CMS, in cooperation with the dedicated cancer hospitals, to seek a change in law that would protect cancer hospitals’ TOPs.

Finally, the AHA supports CMS’s proposal to annually recalculate the PCR of each cancer hospital, the weighted average PCR of the other hospitals and the cancer hospital payment
This is consistent with a recommendation that the AHA made in its CY 2011 OPPS proposed rule comment letter. We believe annual recalculation would ensure more equitable payments.

**OPPS: WAGE INDEX FLOOR OPTIONS**

In the proposed rule, CMS raises concerns about hospital actions involving the inpatient PPS wage index rural floor that have resulted in significant wage index disparities. The agency notes that the law does not require it to use the inpatient PPS wage indexes in the outpatient PPS, and as such, is considering using a modified version of the inpatient PPS wage indexes instead, which the agency claims would address its concerns about the rural floor. Therefore, CMS requests public comment on a number of options it is considering.

The area wage index is greatly flawed in many respects. It is highly volatile from year to year, is self-perpetuating (in that hospitals with low wage indexes are unable to increase wages to become competitive in the labor market) and is based on unrealistic geographic boundaries. These fundamental problems warrant a full and comprehensive re-evaluation and redesign of a system that CMS itself acknowledges is burdensome and of questionable integrity.

There is a great deal of activity around the hospital wage index. In April, CMS issued a report by its contractor, Acumen, on an alternative wage index methodology and solicited public comments. In June, the Institute of Medicine (IOM) issued a report containing recommendations for CMS on the wage index and the geographic practice cost index. The IOM’s report took an entirely different approach and consequently had recommendations that departed significantly from those made in the Acumen report. Also, the IOM announced that it will issue follow-up reports to its June main technical report. In addition, the ACA requires that CMS provide a plan to Congress by December 31, 2011, to comprehensively reform the Medicare hospital wage index.

In recognition of the substantial challenges entailed in revising such an imperfect wage index, in July 2011, the AHA Board of Trustees created a Wage Index Task Force to further examine the issue and analyze reports that the IOM and CMS are required to complete. The Task Force plans to consider the rural floor issue in its deliberations. Therefore, we urge CMS to provide more detail on the multiple options it set forth to address its concerns about the rural floor. In particular, one option CMS sets forth that appears to hold promise is to adopt a decision rule for when the rural floor should not be applied in the outpatient PPS because it will have a disproportionate impact. While we prefer not to perpetuate the current flawed wage index system, we cannot formulate a policy position on this option given the lack of detail provided. Doing so could result in many unintended consequences. Therefore, CMS should provide more information on this option — indeed, all of the other options — in the final rule, including what decision rule it would implement, what it would consider a disproportionate impact, and an impact analysis. In addition, such details would greatly inform the Task Force’s deliberations and leave it better able to fully consider this issue.
PAYMENT POLICY FOR SPECIFIED COVERED OUTPATIENT DRUGS

The Medicare Modernization Act of 2003 (MMA) requires CMS to use special classification and payment for certain separately paid drugs and biologicals that had previously received pass-through payments. Payment for these specified covered outpatient drugs (SCODs) must be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs. Consistent with its 2011 policy, CMS proposes to apply the SCOD payment methodology to all other separately payable drugs and biologicals for which average sales price (ASP) data exists.

For 2012, CMS proposes to again use its revised methodology adopted in the 2010 final OPPS rule to pay for the drug acquisition and pharmacy overhead costs of separately payable drugs and biologies, arriving at a proposed rate of ASP plus 4 percent. This rate is lower than the ASP plus 5 percent rate paid in 2011. To arrive at this rate, CMS first applies its standard drug payment methodology, using hospital claims data and cost reports to estimate the cost of separately payable drugs, which would have resulted in a payment rate of ASP minus 2 percent. Then, CMS made a payment adjustment that redistributes pharmacy overhead costs, in the amount of $215 million, from packaged drugs to separately payable drugs. The $215 million consists of $161 million from the packaged coded drug cost and $54 million from the packaged uncoded drug cost. This boosts the proposed payment rate for separately payable drugs to ASP plus 4 percent.

In order to make this redistribution budget neutral within drugs and not reduce payments for other services, CMS proposes to reduce payments for packaged drugs with an ASP by 35 percent and the cost of packaged drugs and biologicals without a HCPCS code or an ASP by 11 percent.

CMS further proposes to continue to include the claims data for 340B hospitals in the calculation of payment for drugs and biologicals under the 2011 OPPS and that 340B hospitals would be paid the same amounts as hospitals that do not participate in the 340B program for separately payable drugs and biologicals.

The AHA appreciates CMS’s recognition of flaws in its current rate-setting methodology. We also agree that it is important to pay for separately payable drugs in a manner that is administratively simple. However, the AHA believes that the reallocation of $215 million and the resulting payment rate of ASP plus 4 percent is inadequate.

Therefore, the AHA continues to recommend that CMS pay for separately payable outpatient drugs at least at the rate at which they are paid in physician offices – ASP plus 6 percent. Paying for separately payable drugs under the OPPS at a lower rate than drugs provided in physician offices could create inappropriate incentives to treat patients in one setting versus another. CMS should eliminate the inconsistency of paying differently for the same drugs based on the treatment setting. Further, paying for drugs at less than ASP plus 6 percent fails to cover acquisition cost, let alone pharmacy services and handling.

The Social Security Act, at Section 1833(t)(14)(A), requires CMS to reimburse for these separately paid drugs at a rate that is equal to the average acquisition cost for the drug for a year,
as determined by Government Accountability Office (GAO) or CMS surveys of hospital acquisition cost. The law goes on to state that if hospital acquisition cost data are not available, CMS is to pay at the rates applicable in physicians’ offices – ASP plus 6 percent or the rates set under the competitive acquisition program (CAP). Thus, CMS has the authority to pay for separately payable drugs at ASP plus 6 percent. Since neither the GAO nor CMS has conducted surveys of hospital acquisition costs since 2004, and the methodology CMS proposes to use is not a survey but rather is based on an uncertain extrapolation from claims data and a redistribution of a largely arbitrary amount of the pharmacy overhead cost from packaged drugs to separately payable drugs, the AHA recommends that CMS take the option permitted under law and pay at the rate of ASP plus 6 percent.

Due to the instability of CMS’s methodology, the AHA urges the agency to abandon its current approach and default to the other option provided by Congress – to pay for separately covered outpatient drugs at a minimum of at least the rate paid in physicians’ offices, ASP plus 6 percent.

**CODING AND PAYMENT FOR CRITICAL CARE SERVICES**

For CY 2010 and in prior years, CMS has interpreted the critical care CPT codes 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes) and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service)) to include a wide range of ancillary services such as electrocardiograms, chest x-rays and pulse oximetry.

For CY 2011, the AMA CPT Editorial Panel revised its guidance for the critical care codes to specifically state that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines began reporting all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. Because the proposed CY 2012 median costs for critical care services are based upon CY 2010 claims data, which reflect the CPT billing guidance that was in effect prior to CY 2011, CMS is proposing to continue the methodology established in the CY 2011 OPPS/ASC final rule calculating a payment rate for critical care services based on historical data, into which the cost of the ancillary services is intrinsically packaged. CMS is proposing to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

As stated in the CY 2011 OPPS final rule, hospital claims data from CY 2009 for critical care services include charges for any ancillary services provided as part of the critical care services. Therefore, any ancillary services reported on the same date of service should be considered to have been provided outside the critical care period. For example, a patient may have been seen in the emergency department (ED) and ancillary services may have been provided, but the patient did not qualify for critical care services until later in the stay. Conversely, a patient may
have arrived in the ED requiring critical care and have been stabilized; additional ancillary services may have been performed during an observation period, and the patient may then have been transferred to another facility.

We recommend that a modifier be implemented to allow the identification of ancillary services provided to critical care patients during the same date of service as critical care services, but outside the critical care period, so that those services are not inappropriately packaged into the critical care services payment.

Going forward, we recommend that CMS, in setting the payment rate for packaging ancillary services into the critical care services, establish a methodology that includes review of multiple cost report revenue centers. For example, the critical care service provided in the ED would be reflected in the ED cost report line. However, costs for ancillary services (e.g., chest X-ray, EKG, ventilator management) would be reflected in the revenue centers for the respective departments providing the service, such as Radiology, Cardiology, and Respiratory Therapy, for example.

We recommend that CMS consult with the hospital field on the appropriate methodology used to calculate the actual cost related to the provision of critical care services.

**OPPS: HOSPITAL VISITS**

Since April 2000, hospitals have been using the American Medical Association’s (AMA) CPT evaluation and management (E/M) codes to report facility resources for clinic and ED visits. Recognizing that the E/M descriptors, which were 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 that CMS implement national hospital E/M visit guidelines based on the work of an independent expert panel comprising representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience.

For 2012, as it has for every year since implementing OPPS, CMS proposes that until national guidelines are established, hospitals should continue to report visits according to their own internal hospital guidelines to determine the different levels of clinic and ED visits. In the proposed rule, CMS notes its continued expectation that hospitals’ internal guidelines should comport with the principles listed in the 2008 OPPS/ASC final rule. Hospitals with more specific questions related to the creation of internal guidelines are to contact their local fiscal intermediaries or Medicare Administrative Contractors.

The AHA is deeply concerned that CMS does not appear interested in developing or approving national guidelines for the reporting of hospital ED or clinic visits. Since the implementation of the OPPS, the AHA has advocated for 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. Hospitals are using different methodologies, such as those based on time, interventions, or patient complexity or severity; therefore, each hospital’s reported E/M levels reflects different aspects of hospital resource utilization.

Commercial payers have begun to create their own guidelines and interpretations of hospital ED and clinic visit coding. One such inappropriate policy was adopted by Aetna. The lack of national guidelines places hospitals at risk of having different guidelines for different payers. Such lack of uniformity is complex and burdensome for hospitals, in addition to being an inappropriate source of conflict with commercial payers and auditors. Given CMS’s apparent lack of interest in adopting national guidelines, the AHA urges CMS to partner with the AHA to request that the AMA CPT Editorial Panel create unique CPT codes for hospital reporting of ED and clinic visits based on internally developed guidelines. These codes then could be widely reported by hospitals to all payers.

**PAYMENTS FOR NEW CPT CODES FOR ABDOMINAL AND PELVIC CT SCANS**

In the CY 2011 OPPS final rule, CMS assigned several newly approved CPT codes to APCs following its standard practice. Among the new CPT codes were several combination codes for computed tomography (CT) of the abdomen and pelvis, with and without contrast (CPT 74176, 74177 and 74178). Each of these new codes describes two individual services that are frequently performed together; that is, a patient encounter in which both a CT scan of the abdomen and a CT scan of the pelvis are performed.

For CY 2011, CMS inexplicably assigned these new combination service codes to APC groups that described single services. In comments to CMS, the AHA expressed concern that unless this error was corrected, the decision would result in a significant underpayment for hospital CT services. The AHA recommended that instead, CMS should establish two new APCs into which these CPT codes would be placed, depending on whether or not contrast is used, and that payment should be set at the same amount as CMS would pay for composite APCs 8005 and 8006. In subsequent meetings and discussion with the agency, CMS declined to accept the AHA’s recommendation but indicated that it would revisit the issue in the CY 2012 proposed rule.

Following through on this commitment, in the CY 2012 proposed rule, CMS proposes to establish two new APCs – APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) and APC 0334 (Combined Abdominal and Pelvis CT With Contrast) – to which CMS proposes to assign CPT codes 74176, 74177 and 74178. The AHA supports this proposal as well as CMS’s plan to base the payment rate for each of these new APCs on the costs derived from the predecessor codes that reflect combined services. This policy should allow for more appropriate payment because it will take into account the full cost of both services that are now reported by a single CPT code.
We understand that the AMA’s CPT Editorial Panel will be creating additional combined services CPT codes, some of which may not be announced until after the OPPS proposed rule is issued. We urge CMS to revise its standard practice in these circumstances so as to allow these new codes to be assigned to APCs that appropriately reflect the costs of all services in the combined code. Doing so would help to ensure that the payment for these new combined CPT codes is priced correctly in the first year that they are paid under OPPS.

PROPOSED COMPOSITE APC FOR CARDIAC RESYNCHRONIZATION THERAPY WITH DEFIBRILLATOR

CMS proposes to create a new composite APC 8009, Cardiac Resynchronization Therapy with Defibrillator (CRT-D) Composite and, using its “equitable adjustment authority” outlined in the Social Security Act, to cap the payment rate for the new composite APC 809 at the most comparable inpatient Medicare-severity diagnosis-related group (MS-DRG) payment rate. Specifically, the agency proposes to pay for the new composite APC at the lesser of the APC’s median cost ($38,854) or the inpatient standardized payment amount for MS-DRG 227, Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity ($26,365). Therefore, according to CMS’s proposed methodology, the agency would establish the rate for composite APC 8009 at the MS-DRG standardized payment amount of $26,365.

CMS’s rationale in capping the outpatient payment at the inpatient rate is that “the OPPS payment would, by definition, include fewer items and services than the corresponding IPPS MS-DRG payment” and “ensure appropriate and equitable payment to hospitals because patients who receive these services in the hospital outpatient setting are not as sick as patients who have been admitted to receive this same service in the hospital inpatient setting. Therefore we expect it would be less costly to provide care for these patients, who would also spend less time in the facility.”

The AHA does not believe that it is appropriate to disregard hospital outpatient claims data and limit payment to the rate calculated under an entirely different payment system – the IPPS. Instead, we support the recommendation of the APC Panel that “CMS should set the payment rate for composite APC 8009 and APC 0108 using outpatient claims data only.” Doing so will preserve the integrity of the OPPS system by ensuring consistency and transparency in its rate-setting methodology. Further, we are not convinced that CMS has adequately justified its rationale for this precedent-setting proposal. That is, the agency has not provided any substantive evidence to support its assertion that CRT-D services on an outpatient basis would include fewer items and services than on an inpatient basis, nor that the patients receiving these services on an outpatient basis are not as sick and are less costly than the corresponding inpatients receiving these services. Indeed, the AHA is surprised that CMS has taken this approach given that in the past, it has repeatedly rebuffed attempts by various stakeholders to set payment rates for outpatient services using data or other information obtained outside of the OPPS.
If, however, CMS chooses to finalize the policy of paying at the lesser of the outpatient or inpatient rate for CRT-D services, then the inpatient rate used in the proposed methodology should at least reflect the full payment that hospitals would receive for Medicare inpatients receiving comparable services. That is, the AHA recommends that if CMS finalizes its proposal to cap payment for APC 8009 and APC 0108 at the comparable inpatient rate, then the payment should include not only the base MS-DRG rate, but also additional amounts for capital, a weighted average indirect medical education add-on percentage and a weighted average disproportionate share hospital add-on percentage for hospitals furnishing these services.

**PULMONARY REHABILITATION**

Pulmonary rehabilitation (PR), a multi-disciplinary treatment that includes exercise training, self-management education, and psychosocial and nutritional intervention, is a standard of care for chronic obstructive pulmonary disease and has been incorporated into major guidelines. Since CY 2010, when a new statutory benefit category for PR services became effective, CMS has calculated the payment rate for PR (HCPCS code G0424, assigned to APC 0102) using a median “per session” cost that is simulated from historical hospital claims for pulmonary therapy services. This methodology established a national unadjusted payment rate of $63 in CY 2011.

For CY 2012, CMS reports that it now has a robust set of claims data for PR, and therefore the agency proposes to base payment for this service using the standard median calculation process it uses for most other OPPS services. This would result in a payment of $38 for HCPCS code G0424, a 40 percent reduction for PR services. The AHA is concerned that this rate is inadequate and would not even cover the costs of labor, potentially resulting in the closure of many PR programs. In order to preserve access to this valuable service for Medicare beneficiaries, we recommend that CMS freeze the PR payment rate for CY 2012 at the CY 2011 rate of $63.

In the interim, the AHA recommends that CMS shift PR from the standard cost center to a non-standard cost center methodology in order to provide for more specificity in the cost report, leading to more precise mapping within the OPPS revenue crosswalk. In CY 2009, CMS contractor RTI found that including cardiac rehabilitation in the standard cost center classification did not adequately capture all the legitimate costs of the service, and recommended that CMS adopt a non-standard cost center methodology. Cardiac rehabilitation and PR are very similar services, and CMS has on several occasions indicated the similarities between the two types of programs. We believe that like cardiac rehabilitation, PR costs are not being adequately captured using the standard cost center methodology. We are hopeful that adopting a non-standard cost center methodology will eventually result in more appropriate payment rates for PR.
PARTIAL HOSPITALIZATION PROGRAM SERVICES

Proposed Payment Policy for CY 2012. For CY 2012, CMS proposes to continue to use four separate APCs to pay for Medicare partial hospitalization program (PHP) services, including two APCs for services furnished in CMHCs and two APCs for services furnished in hospital-based PHPs. Payments for hospital-based PHP services would be calculated using only hospital data. CMS proposes to calculate payments for CMHC PHP services using only CMHC claims data.

CMS’s proposed CY 2012 payment rates for both hospital-based and CMHC PHP services would decline significantly. The proposed rates for CMHC Level I and Level II services would decline 27 and 33 percent, respectively. The proposed CY 2012 payment rates for hospital-based PHP services would decline 23 percent for both Level I and Level II services. The proposed rates for hospital-based PHP services are:

- APC 0175, Level I Partial Hospitalization (three services) for Hospital-Based PHPs paid at $157 (compared to the 2011 rate of $205); and
- APC 0176, Level II Partial Hospitalization (four or more services) for Hospital-Based PHPs paid at $183 (compared to the 2011 rate of $238).

CMS attributes the CMHC decline to targeted fraud and abuse efforts implemented by various federal agencies. By contrast, CMS says that $30 of the $46 decrease in the hospital-based PHP median cost is the result of one provider with higher cost data no longer billing Medicare for PHP services.

Such a steep payment reduction for PHP services is untenable. We predict that this will cause many hospitals to reconsider whether they can afford to continue providing these services and will force many PHPs out altogether, with a serious negative impact on patient access to PHP services, particularly in rural areas in which psychiatric services are already in short supply.

In order to ensure continued beneficiary access to hospital-based PHP services, we recommend that CMS set the payment rates for CY 2012 at the CY 2011 rate.

Analysis of PHP Data. The AHA bases this recommendation on rigorous data analysis. Due to concerns about the impact that such a significant decline in hospital-based PHP payment rates for CY 2012 would have on access to care, the AHA together with the National Association of Psychiatric Health Systems (NAPHS) this summer contracted with The Wellington Group to update and expand upon our previous review of PHP data by conducting an analysis of three more recent years of PHP data, including data from 2008, 2009 and 2010. The AHA and NAPHS had previously conducted an analysis of 2003, 2004 and 2006 data, which we used in developing our comments for the CY 2008 proposed rule.

The analysis was done in order to better understand the reason for the decline in PHP median rates and provide insights for policy decisions. We have attached to this comment letter a description of the results of this analysis. The story that the data tell is compelling and directly
leads to our recommendation to stabilize the payment rates for hospital-based PHP services to protect access to services, particularly in rural areas.

The data show that, while initially stable, the aggregate number of PHP service providers has declined since 2008. This decline appears in all four regions of the United States. The number of providers declined by less than two percent from 2003-2006. However, since 2008, not only has the overall number of PHP service providers declined by nearly nine percent, but the mix of providers has shifted significantly. Between 2003 and 2010, the number of hospital-based PHPs dropped by 23 percent while the number of CMHC PHPs increased by 68 percent, at its peak, before declining by nearly 10 percent in 2010. The overall growth in CMHC providers over this period was 52 percent. What is even more striking is that the majority of this growth in CMHC PHPs has occurred in only three states: Florida, Louisiana and Texas.

CMHC providers continue to account for a disproportionate share of the PHP days. Between 2003 and 2009, CMHC days increased a staggering 311 percent, before declining by 30 percent in 2010. However, despite the recent decline, CMHCs still account for nearly 80 percent of all PHP days. While the number of hospital-based PHP days increased modestly between 2003 and 2009, in 2010 the aggregate number of hospital days declined by nearly 16 percent. In the same year, the volume of services per provider dropped for both CMHC (by 23 percent) and hospital-based PHP programs (by 15 percent).

We found that CMHC services are heavily concentrated in only a few states, while hospital-based PHP services are more national in scope. In 2010, seven southern states accounted for 82 percent of CMHC providers, and CMHCs in Florida, Louisiana and Texas accounted for 75 percent of all PHP days nationally. In addition, 28 states do not have any CMHC PHPs, and only 27 percent of states have more than one CMHC. By contrast, hospital-based PHPs are more widely dispersed across states, with the top six states accounting for only 42 percent of hospital providers, and 73 percent of states having more than one hospital-based PHP program. However, the number of states without a hospital-based PHP is growing, nearly tripling from 4 states in 2003 to 11 in 2010 — so that over 20 percent of states no longer have a hospital-based PHP program.

Between 2003 and 2010, rural areas in particular experienced significant declines in the number of PHP providers, with a 65 percent decline for rural hospitals and a 29 percent decline in rural CMHCs. Meanwhile the number of urban CMHCs has experienced a 67 percent increase, with the same three dominant states – Florida, Louisiana and Texas – accounting for virtually all of this growth. However, even in states with a growing number of CMHCs, the overall number of PHP providers has decreased significantly (17 percent) since 2008.

However, hospitals remain committed to CMS’s vision of partial hospitalization as a high intensity service, despite significant volatility in payment rates, program rules and number of providers. Since 2003, hospital-based PHP days with four or more services expanded, going
from 67 percent to 80 percent of total PHP hospital days. The most intense PHP services—those
days with five or more services – rose from 13 percent to 23 percent in the same period.

Measures of financial health also are worth examining when considering the prospect for further
reductions in reimbursement for PHP services. CMHCs reported that in 2010, their payments
were a healthy 163 percent of their costs. However, in the same year, hospital-based PHPs
had an average payment-to-cost ratio (PCR) of 67 percent, far below that of CMHCs and
also significantly below the average of 90.1 percent for all hospital Medicare services.
Further cuts in reimbursement for hospital-based PHP services will inevitably drive these
PCRs even lower, putting access to care even more at risk.

In conclusion, our analysis shows that partial hospitalization payment rates have reached a
tipping point, with both hospital and CMHC providers declining, particularly in rural areas. We
are especially concerned that in rural areas, where access to all mental health services is already
very limited, access to the most intensive outpatient mental health services – hospital-based PHP
services – is at significant risk. If PCRs are any indication, the hospital-based PHP programs
are in a precarious situation. Insufficient payment is undermining the ability of hospitals to
continue to provide this critically important service.

Therefore, in order to ensure continued beneficiary access to hospital-based PHP services,
we recommend that CMS set the payment rates for CY 2012 at the CY 2011 rate. We
believe that this will help stabilize access to these critical services and give CMS sufficient
time to evaluate what is driving the drop in median costs, assess the implications for access
to care and determine whether any changes, legislative or regulatory, need to be made to
the PHP. The AHA remains committed to working with CMS to explore options to ensure that
access to hospital-based PHP services, particularly in rural areas, does not erode any further. As
CMS has noted, hospital-based PHP data have been reliable and predictable and hospital-based
PHPs are national in scope and should be protected.

OUTPATIENT QUALITY REPORTING PROGRAM

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 their full
annual update to the outpatient PPS payment rate. Beginning in 2009, hospitals that fail to report
data incur a 2.0 percentage point reduction in their annual payment update.

Fostering Integration. Creating synergies between the inpatient quality reporting (IQR)
program and the outpatient quality reporting (OQR) program represents one of the biggest
opportunities to foster integration and spur care coordination for patients. As such, we urge
CMS to make a stronger conceptual link between the two hospital reporting programs. We
believe this is an important part of what Congress was seeking to achieve when it adopted
provisions in the ACA to create a National Quality Strategy. The National Quality Strategy
begins with the Secretary selecting national priorities that are intended to be the focal point for
measurement, reporting and financial incentives. The use of a common set of priorities will help
focus providers’ quality improvement efforts on high-leverage, important areas and align the various national reporting programs among different health care providers and settings. A preliminary set of national priorities already exists in the work of the National Quality Forum’s (NQF) National Priority Partners, in which CMS and other federal agencies participate. The goal of the national priorities is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care.

In addition to fostering integration, it is critical that meaningful measures be selected for implementation. One way in which measures are made more meaningful is through public reporting. Including measures on Hospital Compare creates significant investment of provider resources in collecting data and improving performance. Therefore, the measures chosen for public reporting should be important measures that accurately and reliably assess meaningful aspects of care. It is incumbent on CMS to choose the best possible measures for this purpose. Our comments below will aide CMS in selecting the best possible measures. We remain supportive of CMS’s practice of continuing to propose measures well in advance of the payment year affected. One advantage to proposing measures a few years prior to implementation is allowing the public to identify any potential operational issues. Our specific comments on the measures proposed for 2014 and 2015 are outlined below, where we note several operational concerns with the proposals and urge CMS to delay implementation in some cases.

**Quality Measures for CY 2014.** CMS proposes nine measures for the CY 2014 update.

*Surgical site infection (SSI)* – SSIs are very serious occurrences. We support including surgical site infection (SSI) measures in quality reporting programs; however, the proposed SSI measure is only endorsed for the inpatient setting, and therefore it is not appropriate for the OQR program. Though this measure is not appropriate for the OQR program, we recognize the tremendous strides that CMS and the Centers for Disease Control and Prevention (CDC) have recently made toward expanding a surveillance system of infection monitoring across settings of care. Both agencies should be proud of the progress that has been made and should continue to pursue other areas of surveillance for the hospital outpatient setting rather than forcing the SSI measure into the OQR program.

In creating the proposed SSI measure, the CDC intended for this measure to be used only for surveillance in inpatient hospitals for a limited number of surgical procedures. This measure matches well with care delivered in an inpatient setting because the majority of patients stay in the hospital several days post-surgery. However, that is not the case for outpatient surgeries. We are concerned about the specificity of the SSI measure and its ability to accurately capture all infections, given the truncated post-surgery time patients spend in outpatient facilities. Many outpatients are discharged within hours of surgery; therefore, the majority of infections that may be related to the outpatient surgery would not be discovered until well after discharge.

Further, as we have expressed in response to other payment regulations, we remain concerned about the capacity of CDC’s National Healthcare Surveillance Network (NHSN) to handle the influx of data from more than 4,000 outpatient facilities. Approximately 4,000 inpatient PPS
hospitals are required to report a blood stream infection measure to the NHSN this calendar year (data due Aug. 15), and it is too soon to tell if this process has been successful. Additional measures are scheduled for reporting in calendar year 2012. The influx of inpatient PPS data represents a significant new burden on the system, and we are still unsure if the system will be able to handle it. Further, CMS recently finalized NHSN measures for long-term care hospitals and inpatient rehabilitation facilities. In the proposed rule, CMS also includes a NHSN measure for ASCs. Finally, CMS has proposed an NHSN measure for end-stage renal disease facilities. That an additional set of providers, hospital outpatient departments, will need to register for the NHSN, learn how to use it, and begin reporting data may be well beyond the capacity of NHSN.

Diabetes primary care management measure set – While the management of diabetes is an important public health goal, we do not support the use of this set of five diabetes measures in the outpatient setting because is not the appropriate place within the care continuum to manage diabetic care. As we indicated in our comments last year, much of the care provided in the hospital outpatient setting is episodic and fragmented; therefore, measures that target management of diseases are not appropriate. We note that these measures are currently specified and used in the Physician Quality Reporting System (PQRS), where they are appropriate. However, measures that are used in PQRS are not “shelf-ready” for use in other quality reporting programs.

Though there are some outpatient facilities that do provide primary care, there are also several other types of specialty-based clinics, such as dermatology clinics, that do not provide any primary care. To this extent, we have previously asked CMS to work with the measure developer to more narrowly construct the denominator population of these measures to capture only provider-based clinics that are paid under the OPPS and that are a source of primary care in their communities. To our knowledge, this change has not been made to the measures; however, if it has been, we may be able to support these measures. Further, when CMS does begin working with the developer to make these changes to the diabetes measures for the outpatient setting, we ask CMS to consider:

- how lab data will be incorporated;
- how the use of CPT-category II codes (which are not used in OPPS billing) or a corresponding algorithm will be used to convey quality data codes; and
- whether these changes fundamentally alter the measure and therefore need to be re-examined by the NQF.

Cardiac rehabilitation referral to an outpatient setting – This measure calculates the percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced a major cardiac event, such as a heart attack, and received treatment for the event in an inpatient setting. This outpatient measure is meant to be used along with a corresponding inpatient measure for the cardiac event. However, the corresponding inpatient measure has not been proposed for use in the Inpatient Quality Program (IQR). Though we fully support the use of these types of care coordination measures in the OQR program, this measure requires a level of coordination that may only be found in highly integrated care systems; as such, it is more appropriate for
accountable care organizations or comprehensive medical homes. It is inappropriate for the OQR program. This measure may be a good candidate if it is applied with its inpatient measure pair when used in an integrated care system.

Further, we are concerned that while this measure attempts to capture referrals made to the outpatient setting, it fails to monitor the real gap in care – that is, whether the patient complies with the referral. Since many outpatient facilities will not have access to the corresponding inpatient data that are necessary to populate the measure, many cases may be missed in assessing the care delivered in the outpatient setting. Even if the majority of cardiac patients who meet the denominator specifications only receive care within an integrated system, there will still be a significant number of patients who are referred from hospitals outside of the system for follow-up care. The receiving outpatient department may not have access to the data from those non-system hospitals that are required for the 12-month look back period.

Safe surgery checklist structural measure – Select hospitals and health systems have extensively published positive results in reducing surgical errors through a number of interventions, including the use of a surgery checklist. Though the use of a safe surgery checklist may be a process that could lead to reduced surgical errors, the proposal is merely a concept that is not a fully developed measure. Because the proposal is only a concept, it is not a fully developed measure and is not endorsed by the NQF; therefore, it should not be finalized for the OQR program.

However, even though there is not a NQF-endorsed measure for a surgery checklist, there are still many requirements in place to address safe surgeries. CMS has previously issued National Coverage Determinations (NCD) to measure the outcome of this adverse event. In addition to not receiving any reimbursement for any aspect of a surgery that results in an adverse event, the NCDs also require all provider types to notify CMS of adverse surgical events. Further, the Joint Commission surveys all accredited institutions for surgery checklists as part of its patient safety requirements. With these more comprehensive safeguards already in place, adding this concept to the OQR program would introduce an undue burden and actually be a step backwards from progress that has already been made by focusing on surgical outcomes.

Hospital outpatient volume data on selected outpatient surgical procedures – CMS is proposing collection of outpatient volume data for eight surgical procedures because it believes there is a correlation between volume of services and better outcomes. However, the literature supporting the link between procedure volume and outcomes is controversial at best, and we do not support collection of these data because they do not constitute quality measures. Because these data are not quality measures, they are not NQF-endorsed and should not be finalized for the OQR program.

Further, these outpatient data do not meet the peer reviewed definition of an accountability measure. The Joint Commission defines accountability measures as those for which there are large volumes of research linking the measure to improved outcomes; the measure accurately assesses the relevant clinical process; and implementation of the measure has minimal
unintended adverse consequences. This proposed volume data requirement does not meet any of these essential criteria.

**Quality Measures for CY 2015.** CMS proposes one measure for the CY 2015 update.

*Influenza vaccination coverage for health care personnel* – The spread of infectious disease in society is a serious public health concern. Though the incidence of contracting influenza within a health care facility is lower than contracting it within a community, we strongly support processes and procedures that mitigate contraction of influenza in outpatient and all healthcare facilities. As such, we support the public reporting of healthcare worker vaccination rates; however, we are concerned that requiring the collection of this information through NHSN is too labor intensive. **We urge CMS to delay implementation of this measure to allow time for hospitals to work with vendors to support and assist in the submission of data.**

Currently, these data exist within the human resources department of many hospitals but are not easily transferred into the quality reporting system that is already in place. Outpatient facilities need more time than is currently being allotted to work with data vendors to assist with transferring data from human resources departments into NHSN. We note that CMS recently finalized this measure for the IQR program. We urge CMS to work with hospitals over the next year to determine how the process is working prior to mandating this data collection effort for outpatient departments. **Only after CMS and CDC have worked through this new process with inpatient facilities should this mandate be placed on outpatient facilities.**

Further, we understand that this measure is currently undergoing maintenance review by the NQF because the measure was originally endorsed on a time-limited basis. The subsequent testing data that the NQF is reviewing will likely indicate that the measure needs to be resubmitted for full endorsement. Specifically, CDC is currently engaging its advisory panel to help determine several different denominator populations to which this measure will apply. It is likely more than one measure will emerge once the maintenance process is completed. Because this measure is currently in flux at the NQF, we urge CMS to delay finalizing this measure. We encourage CMS to re-propose this measure in next year’s rulemaking.

As noted above, we are fully supportive of publicly reporting this measure when it is ready. To that end, the AHA board of directors recently released a statement in support of influenza vaccination policies within hospitals and health systems:

> America’s hospitals are committed to protecting the health and well-being of patients and staff. Evidence has emerged over the past few years clearly indicating that health care workers can unintentionally expose patients to seasonal influenza if they (the workers) have not been vaccinated, and such exposure can be dangerous to vulnerable patients.

> To protect the lives and welfare of patients and employees, AHA supports mandatory patient safety policies that require either influenza vaccination or wearing a mask in the
presence of patients across health care settings during flu season. The aim is to achieve the highest possible level of protection.

**Additional Comments.**

_Capturing NQF measure status quo in regulation_ – We are concerned at the lack of transparency CMS is exhibiting regarding the NQF-status of OQR program measures, and we implore CMS to include an update on the NQF status of each measure in every proposed and final regulation regarding quality programs. NQF endorsement is an essential component of measure development and implementation. Not only is CMS required to use NQF-endorsed measures within its quality reporting programs (or justify why it chose not to use an NQF-endorsed measure), but HHS also has a 4-year $40 million measure endorsement contract with the NQF. Because of the important role NQF plays in the measure process, CMS must do a better job of delineating the current NQF status of measures that are proposed and finalized in its national programs. The increased transparency of including NQF status for each measure in regulations will allow CMS to receive more informed comments from the public.

For example, this proposed regulation would have benefited from including an account of current NQF status. As we mentioned above, there are significant changes currently underway for the maintenance review of the influenza vaccination measure. Further, in the fall of 2010, the NQF launched a patient safety steering committee to do a maintenance review of the CDC’s measures. Once a measure is endorsed, the NQF will typically review a measure approximately every three years. When the NQF launched the patient safety committee, another measure developer, the National Surgical Quality Improvement Program (NSQIP), also submitted a measure for surgical site infections. The NSQIP measure is an alternative to the CDC’s SSI measure, as both measures pertain to the same population and the same infections. Many stakeholders responded and urged the NQF to select only one best-in-class measure pertaining to surgical site infections. The NQF board of directors determined that a best-in-class decision was appropriate, meaning the NQF would be endorsing either the CDC measure or the NSQIP measure, but not both. No decision has been made for these measures; therefore, the state of endorsement remains in flux. Until NQF makes its final decision, we cannot be sure that the CDC measure will remain NQF-endorsed.

Capturing this level of information is essential to creating an open and transparent regulatory environment when measures are proposed. We note that the NQF is currently pursuing over 200 measures for maintenance endorsement, which amounts to more than one-third of NQF’s total measure portfolio. This is an extensive effort and must be referenced in future rulemaking.

_Previous policy decisions that must be corrected_ – We remain concerned about the imaging efficiency measures that were adopted for use beginning with 2010, and we urge CMS to retire these measures from the outpatient pay-for-reporting program. Of the four initial imaging efficiency measures, none is HQA-adopted, and only two have been endorsed by the NQF. The two measures that have not been endorsed by the NQF, *Use of Contrast: Abdomen CT* and *Mammography Follow-up Rates*, are not only inappropriate for the reporting program, but have the potential to cause patient harm. In fact, the mammography measure was submitted
twice to NQF for endorsement, and both times the NQF Steering Committee declined to advance the measure because of the concern that by promoting lower follow-up rates, the measure could have the unintended consequence of increasing the number of missed cancers.

CMS’s own consumer testing of the website display of the imaging measures repeatedly showed that the measures were difficult to comprehend and did not provide valuable, usable information to consumers. Since the measures were first included on Hospital Compare in July, we have heard additional confusion over what the measures represent and how they should be interpreted. Again, we urge CMS to reconsider the use of these measures and retire them from the outpatient pay-for-reporting program.

QUALITY REPORTING THROUGH EHRs

CMS proposes changes to the regulations governing the Medicare and Medicaid EHR Incentive Programs, and particularly requirements on hospitals to report on 15 specific clinical quality measures (CQMs). Our comments address our overall concerns with automated quality reporting under Stage 1 of Meaningful Use, and then provide specific comments on the proposed pilot.

Overall Concerns with Automated Quality Reporting. Automated quality reporting has clear benefits, including efficient measurement, real-time results and the potential to include whole populations in measure calculations, as well as the ability to easily look at sub-groups. To be useable, however, automated quality measurement must be feasible, generate valid and reliable results and have benefits that outweigh the costs. Early experience in Stage 1 of meaningful use indicates that the current approach to automated quality measurement will not deliver on that promise. Providers and vendors have encountered significant issues with the e-specifications, which contain known errors and have never been field tested. Unfortunately, no structured process is in place to ensure that corrections or updates are communicated and adopted by vendors, such as the addition of new medications to treat patients with stroke. In addition, the existing CQMs require a level of clinical documentation and the use of coded data fields that are far more extensive than the Stage 1 requirements and not in common use. Further, the certification process for EHRs specifically does not include testing the accuracy of the measure calculations. In practice, our members report that the EHR products they have purchased do not generate accurate quality data without significant effort, including use of custom fields and screens, significant training and increased work for clinicians to capture the necessary data during the care process, and even the use of abstractors to fill in missing data elements.

The AHA appreciates the recognition of these issues by CMS and in FAQ #10589, which requires only that providers submit the CQM data generated by their EHR and indicates that the data will not be used for performance reporting. **We would urge CMS to clarify also that the likely inaccurate data currently being generated by certified EHRs and submitted for Stage 1 of meaningful use will not be publicly reported or used as a baseline for future quality reporting programs, such as value-based purchasing. Moving forward, CMS should follow**
standard notice and comment before using quality data reported for meaningful use in other programs.

Given the struggle to operationalize the current quality measures, rather than the limited pilot described in the proposed rule (and discussed below), the AHA urges CMS to conduct a pilot program to field test the measures used in the EHR incentive program and determine the ability of vendors and hospitals to accurately capture the necessary data in the required formats to generate valid, reliable and comparable quality measures directly from the EHR. In addition, CMS should establish a clear process to manage updates to specifications for quality measures, and a mechanism through which vendors and providers can provide feedback on problematic or unclear measures.
The following chart illustrates the process CMS and the quality measurement field should follow to develop automated clinical quality measures that will result in comparable data across hospitals. It emphasizes the need to consider up front whether a measure can be automated or requires a level of clinical judgment that makes automation difficult; the need for field testing to determine whether the needed data are in the EHR and vendor products can capture it; the need for validation that vendor products can, in fact, accurately calculate the measures based on test data sets; and the need for a structured feedback and update process.

**Comments on the Proposed Electronic Reporting Pilot.** CMS proposes to require hospitals to continue using web-based attestation for reporting quality data required for the Medicare EHR incentive program in fiscal year 2012, rather than requiring electronic submission directly from the EHR. The required measures would not change. In addition, CMS proposes to begin a voluntary Electronic Reporting Pilot in 2012 to test automated reporting of the quality measures required under the EHR incentive program. While the same 15 quality measures would be used in the pilot, the actual data submitted to CMS would be different. CMS proposes that rather than
submitting summary measure data (numerator, denominator and exclusions), as currently required, hospitals participating in the pilot would submit a full year of Medicare patient-level data, from which CMS proposes to calculate the CQM results itself, using a uniform calculation process.

The pilot test would also involve use of data transmission standards other than those currently supported by certified EHRs because CMS has concluded that “it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry content exchange standards as required for certified EHR technology.” CMS anticipates that the pilot will instead test use of the Health Level Seven (HL7) standard Level 1 Quality Report Document Architecture (QRDA), which has been developed to support reporting on quality data from EHRs. We ask CMS to work with the Office of the National Coordinator for Health Information Technology to remove the PQRI 2009 Registry content exchange standards from the certification requirements, as they will not be used.

The AHA appreciates and supports the proposed pilot project to test a new standard for transmission of automated clinical quality data from EHRs. We also urge CMS to adopt its proposal giving hospitals a choice of how to meet their meaningful use quality reporting requirements – through attestation, through participation in the pilot or through both attestation and participation in the pilot (Federal Register page 42335) and to ensure that the regulatory language clearly outlines these options. This policy is especially important in 2012, when almost all hospitals that attest will be in their first year of participation in the EHR incentive program, with a 90-day reporting period. A pilot program that required hospitals in their first year of the program to report a full-year of data for the quality measures would delay their receipt of incentive payments by up to nine months, and significantly discourage participation in the pilot. The agency may, in fact, want to consider going one step further, and allow hospitals to participate in the pilot program even if they are not ready to attest to meaningful use in 2012.

While the AHA supports the pilot concept, we have significant concerns with the proposal presented, and would recommend a different kind of pilot be conducted that focuses on whether EHRs can accurately generate quality measure data that is valid, reliable, and comparable across hospitals. The pilot, as described, would collect large volumes of Medicare patient-level data from hospitals, rather than collecting measure data (numerator, denominator and exclusions). This approach breaks from a number of principles for quality measurement that have been developed since hospitals began reporting quality data to CMS.

First, hospital quality measures have historically been collected on all patients, not just Medicare patients, an approach that is best for capturing the quality of care delivered to all patients, and is currently used in all of the existing hospital quality reporting programs under Medicare. We recommend that any quality reporting pilot include all patients in the measure calculations.
Second, we are concerned that the pilot program puts forward an approach that takes away a key benefit of quality measurement through EHRs – real-time data on performance. If quality measures are calculated by the individual hospital using its EHR, then results can be presented to clinicians immediately, tracked on an ongoing basis, and used to support quality improvement activities. If instead the hospital sends patient-level data to CMS for measure calculation, then waits for the agency to provide feedback on performance, the data become much less timely and less useful for ongoing quality improvement efforts. We urge CMS to structure any quality reporting pilot to focus on the ability of EHRs to provide real-time measurement data to hospitals and physicians.

Third, we are concerned about the volume of data that CMS is proposing to collect, particularly if it is brought to a national scale after the conclusion of the pilot. The measures currently used in the meaningful use program include all patients admitted from the ED, as well as all patients treated for stroke and, in the case of the measures on care for venous-thrombolytic embolisms (blood clots), all admitted patients age 18 and over. Creating an analytic file that has the full patient records for all of those patients for an entire year will take considerable resources to generate. We also question whether CMS has the capacity to receive and analyze the full set of these large data files across hospitals. For example, according to the CDC, there are more than 120 million ED visits in the U.S. annually, and AHA data indicate that there are more than 35 million inpatient admissions annually. We recommend that CMS focus on collection of measure data (numerator, denominator and exclusions), not patient-level data. Providers, however, should have the choice to work with private-sector intermediaries to generate measure data elements if they choose to work with third-party vendors to abstract information from electronic data sources.

Fourth, CMS has not previously received such large amounts of protected health information from hospitals, and we are concerned about the potential risks to the security of patient data. In fact, under current quality reporting programs, CMS does not receive any patient-level data. Under the Inpatient Quality Reporting program, hospitals submit data to a Quality Improvement Organization (QIO) clinical data warehouse. The QIO warehouse serves as a third-party vendor to transmit performance on quality measures to CMS. QIO data are protected under the law, and therefore CMS does not directly access any patient-level data. We urge CMS to build a similar protection into the EHR pilot program.

AMBULATORY SURGICAL CENTER ISSUES

ASCs: Quality Reporting Program. The Tax Relief and Health Care Act of 2006 (TRHCA) authorizes CMS to implement a program under which ASCs must report data on the quality of care in order to receive the full annual update to the ASC payment rate. ASCs failing to report the data will incur a reduction in their annual payment update factor of 2.0 percentage points. For the first time, CMS proposes 11 quality measures to begin the ASC Quality Reporting Program. We have been urging CMS to begin the ASC Quality Reporting Program since TRHCA was signed into law. Though we support the implementation of this new quality
program, we are concerned with CMS’s approach. **CMS is proposing measures that have not be tested for use in ASCs.** Our detailed comments on the proposed measures for CY 2014 through 2016 are included below.

**CY 2014 Proposals**

CMS proposes eight measures for the CY 2014 update.

Quality measures reported through claims data. CMS is proposing the submission of seven measures through the claims data process. These measures are all NQF endorsed; however, CMS intends to alter these measures so they can be submitted through claims data. In the proposed rule, CMS states:

> We are proposing to require ASCs to report on ASC claims a quality data code (QDC) to be used for reporting quality data. We are proposing that an ASC would need to add a QDC to any claim involving a proposed claims-based quality measure.

Our concerns do not pertain to the seven proposed measures but to the new, untested data reporting mechanism that CMS is proposing to use for ASC data submission. A critical component of the NQF endorsement process is sufficient testing of a measure. CMS’s proposal to create this new QDC reporting code represents a fundamental change to the measures that has not been tested. As such, **it is incumbent upon CMS to re-submit these measures to NQF.** Once NQF has approved the re-submitted measures, we may be able to support them; however, we cannot support them at this time.

Further, we note that this is not the first time CMS has gone down the path of requiring QDCs through claims data submission. CMS first began the Physician Quality Reporting System with the same data submission process, which yielded less than optimal results. Even after nearly five years of operation, CMS still has not worked out all of the QDC problems. Professionals are still using the QDC method in the PQRS program and, as a result, may not receive a bonus payment because of failure to properly submit data. Even though there are problems with the QDC submission process, eligible professionals have found much greater success with reporting through registries and a tool CMS has developed – the group practice reporting option tool. If CMS intends to borrow data submission mechanisms from PQRS for the ASC program, we urge CMS to consider these mechanisms rather than QDCs.

Surgical site infection (SSI). CMS is proposing one SSI measure for ASCs. This measure was also proposed for the OQR program. Our OQR comments also apply to ASCs and therefore, we refer CMS to our OQR comments.

**CY 2015 Proposals**

CMS proposes two quality measures for CY 2015 on safe surgical checklist and volume of ASC surgical procedures. Both of these measures were also proposed for the OQR program. Our OQR comments also apply to ASCs and therefore, we refer CMS to our OQR comments.
CY 2016 Proposals

CMS proposes one measure for CY 2016 on influenza vaccination of healthcare personnel. This measure was also proposed for the OQR program. Our OQR comments also apply to ASCs and therefore, we refer CMS to our OQR comments.

ASC: Cost Reporting. Under the methodology of the ASC payment system, ASC cost information is not used to set and revise ASC payment rates. Instead, CMS relies on the relativity of hospital outpatient costs developed for the OPPS. The Medicare Payment Advisory Commission has again recommended that ASCs should be required to submit cost data to the Secretary to allow for an effective evaluation of the adequacy of the ASC payment rates.

The AHA continues to urge CMS to require ASCs to begin to routinely report cost data to allow for future validation of the relative appropriateness of ASC payment weights and rates. This could be accomplished through implementing an ASC cost-reporting system or through the periodic collection of ASC cost data at the procedure level.

Physician Self-Referral Prohibitions and Patient Notices

The proposed rule contains the remaining required regulations to implement the ACA ban on physician self-referral to new physician-owned hospitals using the whole hospital or rural exceptions – those setting out the process and criteria for requesting an exception to the ban on growth by grandfathered existing physician-owned hospitals. The notice also includes proposed revisions to the patient notice requirements adopted in 2008 for hospitals that do not have physicians on their premises 24 hours a day, 7 days a week (24/7).

Exceptions to the Growth Ban. The AHA agrees with and supports the overall approach taken by CMS. It closely follows the statute and lays out a straightforward process that balances efficient processing with the statute’s requirements, especially those regarding public and community input on CMS decisions to grant exceptions. We would not support the elimination of any of the steps in the process. The process includes the following steps:

- Submission of a request to CMS that demonstrates compliance with the eligibility criteria and prominent posting on the hospital’s website of a notice that a growth request has been submitted. The notice must remain there until a final decision is made by CMS.
- Posting of a notice by CMS on its website, an announcement of the request through the CMS hospital listserv, and publication of a notice in the Federal Register with a 30-day comment period.
- Acceptance of the request as complete at the end of the 30-day comment period if no comments are received. If comments are received, CMS will provide them to the requesting hospital, which then has 30 days to provide documentation and information to CMS to rebut the comments.
• Rendering of a decision by CMS no later than 60 days after the application is certified as complete. Decisions will be posted on CMS’s website, including the identification of the hospital and the size expansion approved.

With regard to some of the specific issues raised by CMS in the notice, we have the following comments.

*Data used to determine eligibility.* The AHA supports the proposed use of standardized data sets (predominantly the CMS Healthcare Cost Report Information System (HCRIS) and the Bureau of the Census) to determine eligibility for a grandfathered physician-owned hospital to expand. Use of common data sets for all requests will minimize inconsistent application of the eligibility criteria. The criteria for granting a general request to expand the number of beds, operating rooms or procedure rooms relate to whether:

- There is significant growth in the area population;
- Hospital bed capacity is low and bed occupancy is high in the area;
- Medicaid inpatient admissions at the requesting hospital are at or above the annual percent level in other hospitals in the county;
- The requesting hospital does not discriminate against federal health care programs and does not permit physicians practicing at the hospital to discriminate against the beneficiaries of those programs; and
- The request would not exceed the absolute limit of growth (200 percent of licensed beds, operating rooms and procedure rooms on the date of enactment).

*Use of Parallel Process for Exception Requests by High Medicaid Hospitals.* The AHA also supports CMS’s decision to use the same process, data bases, and limit on total growth for both general growth requests and requests by high Medicaid hospitals. Under the ACA statutory provisions, high Medicaid hospitals (those with the highest percentage of Medicaid inpatient admissions in a county that has at least two hospitals) are not required to meet the population growth and occupancy criteria that would otherwise apply. CMS has chosen to apply parallel requirements for high Medicaid hospitals, other than the statutorily-altered eligibility criteria. We believe that this is consistent with statutory intent and will minimize any confusion or mistakes in submitting applications. Processing requests should also be more efficient and consistent.

*Patient Notices.* The AHA supports CMS’s decision to roll back provision of the physician availability notice to outpatients except when the services furnished involve observation, surgery or any other procedure requiring anesthesia. These requirements apply to all inpatient facilities, not just those that are physician-owned. When originally adopted, such hospitals were required to provide all inpatients and outpatients at the facility with a notice about the lack of 24/7 physician availability and how they would handle emergencies in the event that a physician was not available when needed. From the beginning, AHA has opposed providing the
notice to all outpatients as overly burdensome and unnecessary except in these limited circumstances.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President
Partial Hospitalization
Insights And Implications

American Hospital Association
and
National Association of
Psychiatric Health Systems
Declining median costs for partial hospitalization have raised questions and concerns for CMS, providers and their associations.

- CMS changed its payment policies for partial hospitalization for 2009 by focusing on the number of services per day.
- AHA and NAPHS have updated the previous partial hospitalization analysis for 2008-2010 in an effort to reassess the issues and provide insights for policy decisions.
Partial Hospitalization Is Dominated By Only A Few Services

<table>
<thead>
<tr>
<th>Service Description</th>
<th>2003</th>
<th>2004</th>
<th>2006</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>90853/G0410 Group psychotherapy</td>
<td>2,083,666</td>
<td>2,363,576</td>
<td>3,292,412</td>
<td>4,920,061</td>
<td>5,991,906</td>
<td>4,247,717</td>
</tr>
<tr>
<td>G0177 Training and education services</td>
<td>405,663</td>
<td>532,292</td>
<td>900,109</td>
<td>1,173,819</td>
<td>1,904,922</td>
<td>1,365,979</td>
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<tr>
<td>90857/G0411 Interactive group psychotherapy</td>
<td>292,964</td>
<td>372,088</td>
<td>538,926</td>
<td>529,155</td>
<td>825,923</td>
<td>713,350</td>
</tr>
<tr>
<td>G0176 Activity therapy</td>
<td>279,163</td>
<td>295,737</td>
<td>367,608</td>
<td>387,738</td>
<td>447,653</td>
<td>399,516</td>
</tr>
<tr>
<td>90816 Individual psychotherapy 20-30 min</td>
<td>31,309</td>
<td>29,785</td>
<td>31,271</td>
<td>40,381</td>
<td>40,672</td>
<td>36,353</td>
</tr>
<tr>
<td>G0129 Occupational therapy</td>
<td>29,965</td>
<td>32,164</td>
<td>23,259</td>
<td>16,585</td>
<td>17,110</td>
<td>13,826</td>
</tr>
<tr>
<td>90818 Individual psychotherapy 40-50 min</td>
<td>26,849</td>
<td>25,727</td>
<td>23,913</td>
<td>24,170</td>
<td>24,820</td>
<td>21,423</td>
</tr>
<tr>
<td>90801 Psychiatric diagnostic examination</td>
<td>9,929</td>
<td>10,647</td>
<td>11,700</td>
<td>10,442</td>
<td>12,268</td>
<td>12,811</td>
</tr>
</tbody>
</table>

Number of services reported, excluding quantities of 10 or more
Regionalization
While Initially Stable, Providers Have Steadily Declined Since 2008 ...

- The number of providers declined by less than 2% from 2003-2006
- The number of providers declined nearly 9% since 2008
... And The Mix Has Shifted Significantly

- Hospital providers declined by 23%
- At their peak, CMHC providers increased by 68%, before declining by nearly 10%
  - Florida, Louisiana and Texas accounted for almost all of the change in CMHCs
... And CMHCs Account For A Disproportionate Share Of The Days

- CMHC days increased by 311% from 2003-2009, before declining by 30% in 2010
- Despite the recent decline, CMHCs still account for nearly 80% of the days
- Hospital days decreased by almost 16% from 2009 to 2010
CMHCs Are Concentrated In Southern States …

- In 2010, seven southern states (FL, LA, TX, AL, MS, TN, and GA) accounted for 82% of CMHC providers.

![Bar chart showing top states for CMHCs.](image)
... While Hospitals Are More Dispersed ... 

In 2006, the top six states accounted for only 42% of hospital providers.

Ten southern states represent only 28% of hospital providers.

<table>
<thead>
<tr>
<th>Top States For Hospitals</th>
</tr>
</thead>
</table>
| California               | 50  
| Texas                    | 26  
| Massachusetts            | 25  
| Illinois                 | 23  
| Michigan                 | 21  
| Pennsylvania             | 20  
| New York                 | 15  
| New Jersey               | 15  
| Louisiana                | 15  
| Georgia                  | 15  
| Florida                  | 15  
| Other                    | 149 |
... But Just A Few States Account For The Vast Majority Of The PH Days

- Florida, Louisiana and Texas account for 75% of partial hospitalization days nationally.
Access
CMHCs Are Unevenly Distributed Geographically ...

- More than half of states do not have a CMHC
- Only 30% of states have more than one CMHC
... While Hospitals Are More Widely Dispersed

- 73% of states have more than one hospital program
- However, the number of states without a hospital program has nearly tripled since 2003
Rural Areas Experienced Significant Reductions In Providers ...

- Locations losing providers
  - 29% decline for rural CMHCs
  - 65% decline for rural hospitals
  - 15% decline for urban hospitals

- Urban CMHCs are the only group that is growing
  - 67% increase
  - However, Florida, Louisiana and Texas account for almost all of the growth
...But Even The Growth States Have Reached A Tipping Point ...

- The number of providers peaked in 2008
  - Florida has declined by 21%
  - Louisiana by 4%
  - Texas by 2%

- Proposed rate reductions will likely lead to increased access issues
... Resulting In Fewer Providers In All Regions Since 2008

- In the South, the growth of CMHCs has masked a 24% reduction in hospital programs from 2003-2010
- In 2010, seven of thirteen states in the West had no providers and another had only one
Divergent Strategies
CMHC Strategy Shifted Dramatically As CMS Changed Payment Policies …

- CMHCs reduced service intensity from 2003-2008
  - Days with 1-3 services doubled from one-third to two-thirds of CMHC days
  - Days with five or more services decreased from 30% to 8%
- In response to new service requirements and rates, CMHCs increased service intensity
  - Days with 4 or more services now represent almost 98% of CMHC days
... And Increased Volume Significantly ...

- Days per CMHC increased by 148% from 2003-2009, before declining by 23% in 2010
- Days per hospital increased by 47% from 2003-2009, before decreasing by 15% in 2010
While Hospitals Consistently Increased Their Service Intensity...

- Hospitals remained committed to CMS’ vision of partial hospitalization as a high intensity service despite volatility in payment rates.
  - Days with four or more services expanded from 67% to 80% of hospital days.
  - Days with five or more services increased from 13% to 23%.
... Resulting In Widely Divergent Payment To Cost Ratios

![Payment To Cost Ratio Chart]

- The payment to cost ratio for hospitals (.67) is well below the OPPS average of .90
- Further rate reductions will drive the payment to cost ratio even lower and reduce access even more
Conclusions

- Partial hospitalization has reached a tipping point
  - Both hospital and CMHC providers are declining, particularly for rural areas
- Payment to cost ratio for hospitals is far below the OPPS average
- Reduced payment rates will contribute to fewer providers and increased access issues