American Hospital Association

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August 31, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1504–P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: CMS-1504-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to the ASC Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for GME Costs; and Proposed Changes to Physician Self-Referral Rules; Proposed Rule (Vol. 75, No. 148), August 3, 2010.

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS), ambulatory surgical center (ASC), graduate medical education costs and physician self-referral proposed rule for 2011.

We provide detailed comments on several proposals in the attached document. The AHA has serious concerns about CMS' proposal for supervision of outpatient therapeutic services, the methodology for calculating the cancer hospital adjustment, the requirements for outpatient quality data reporting, the payment rates for separately payable drugs, the continuing failure of CMS to require ASC quality and cost reporting and the lack of information needed to comment on the ASC productivity adjustment factor. Additionally, we oppose the application of the multiple procedure payment reduction to therapy services, and provide greater detail on this provision in our comment letter on the Medicare physician fee schedule proposed rule. In brief, the AHA makes the following recommendations:

- While the AHA appreciates CMS' efforts to respond to critical access hospital's (CAHs') concerns and its attempt to provide additional flexibility, we do not believe that the proposed supervision policy for outpatient therapeutic services will provide substantive regulatory relief for CAHs or other hospitals.

  - The AHA recommends a more comprehensive and clinically appropriate approach for providing supervision for therapeutic services that we believe will provide for high-quality and safe patient care without hampering access through unnecessarily onerous requirements for less risky and complex services.

  - Until the more comprehensive policy is established and implemented, the AHA recommends that CMS extend the direct supervision enforcement moratorium for CAHs through 2011 and also apply the moratorium to other small and rural hospitals.

  - In addition, the AHA continues to disagree with CMS' repeated assertion that it has required direct supervision for all outpatient therapeutic service, 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 CMS revise its proposed methodology for calculating the cancer hospital adjustment to include cancer hospitals' expected transitional outpatient payments.

- 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.

- We recommend that CMS abandon its current methodology for calculating the payment rate for separately covered outpatient drugs due to its instability. Instead, the agency should pay for the acquisition cost of separately covered outpatient drugs at the rate at which they are paid in physician offices, currently ASP plus 6 percent. The law permits CMS to use this payment rate as an alternative.

- Given CMS' lack of interest in adopting national guidelines for the reporting of hospital emergency department (ED) or clinic visits, we urge CMS to support a request to the American Medical Association CPT Editorial Panel to create unique CPT codes for hospital reporting of ED and clinic visits based on internally developed guidelines.

- We support CMS' proposal to continue to use only hospital data to set payment rates for hospital-based partial hospitalization program (PHP) services. Further, the AHA urges CMS to carefully consider the possible implications for hospitals and patients of CMS' proposed policy for paying for community mental health centers (CMHCs) PHP services and consider phasing-in the payment reductions for CMHC-based PHP services over a few years.

- In the interests of transparency and equity, we continue to urge CMS to implement a quality reporting system for ASCs as soon as possible. Also, in order to allow for future validation of the appropriateness of ASC payment weights and rates, we continue to recommend that CMS require ASCs to begin to routinely report cost data.

- Before implementing the multifactor productivity adjustment to the ASC payment system and to the other payment systems, which will cut billions of dollars from providers, CMS should fully disclose the methods and data sources used for this estimate for public comment.

- CMS should not eliminate residency slots from hospitals unless they are training below their residency caps in all three of the most recent cost reporting years.

- The AHA recommends that CMS continue to adhere closely to the statutory language of Sec. 6001 of the *Patient Protection and Affordable Care Act* that addresses the whole hospital and rural provider exceptions to the physician self-referral prohibition and related congressional intent.

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,

Rick Pollack
Executive Vice President

Attachments

American Hospital Association

Detailed Comments on the Outpatient PPS, Ambulatory Surgical Center, Graduate Medical Education and Physician Self-Referral Proposed Rule for CY 2011

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PROPOSED POLICIES FOR SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES

For calendar year (CY) 2011, CMS proposes "modest" changes to its supervision policy for outpatient therapeutic services that would apply to all hospitals, including critical access hospitals (CAHs). Specifically, CMS identifies a small set of "nonsurgical extended duration therapeutic services" for which a new hybrid level of supervision is proposed. For these services, CMS proposes to require direct supervision at the initiation of the service followed by general supervision for the remainder of the service.

CMS' proposed change to its direct supervision policy takes a very small step in the right direction, primarily because the agency is finally acknowledging that not all services covered by Medicare in hospital outpatient departments require direct supervision. **However, the agency's proposal does not go nearly far enough to assure continued access to the full range of outpatient therapeutic services in hospitals, particularly for small and rural facilities, such CAHs.** There are many other procedures that can be, and are, safely furnished in hospital outpatient departments under the general supervision of a physician.

While our response addresses some of the issues for which CMS is seeking feedback, our comments below also propose a more comprehensive and clinically appropriate approach for providing supervision for therapeutic services that we believe will preserve high-quality and safe patient care without hampering access through unnecessarily onerous supervision requirements. Because a more comprehensive supervision policy will take time to establish, and, in the meantime, CAHs and other small and rural prospective payment system (PPS) hospitals are largely unable to comply with the requirements of the new supervision regulations, we recommend that CMS extend through 2011 the enforcement moratorium currently in place for CAHs and also apply it to other small and rural PPS hospitals. At a minimum, CMS should retain the moratorium for CAHs and extend it to other hospitals located in communities with shortages of health professionals. In addition, the AHA continues to disagree with CMS' 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.

Proposed Supervision Requirements for "Nonsurgical Extended Duration Therapeutic Services"

In the rule, CMS defines a set of 16 "nonsurgical extended duration therapeutic services" as those services with a significant monitoring component that can extend for a sizable period of time, are not surgical and typically have a low risk of complication. CMS proposes that these services would be subject to direct supervision only for the initiation of the service followed by general supervision for the remainder of the service. CMS proposes to adopt the definition of "general supervision" used for diagnostic services, meaning that the procedure is furnished under a physician's overall direction and control, but the physician's presence is not required when the procedure is performed.

CMS describes this policy as the agency's response to the significant correspondence and concerns voiced by CAHs and rural hospitals, and a way to offer flexibility within the supervision requirements while continuing to ensure that Medicare-purchased outpatient therapeutic services are delivered with a "basic level of quality and safety" and consistent with *Social Security Act's* requirements that these are "incident to" physician services. According to CMS, the services that CAHs identified as particularly challenging from the direct supervision perspective included observation and chemotherapy, which have extended duration and a significant monitoring component that could extend after business hours. By proposing to allow a reduced level of supervision to apply for a portion of some of these services, CMS believes that it is providing flexibility to CAHs and to other hospitals.

While the AHA appreciates CMS' efforts to respond to CAHs' concerns and its attempt to provide additional flexibility, we do not believe that the policy as proposed will provide substantive regulatory relief for CAHs or other hospitals. This is because, as CMS itself notes, the longstanding practice in CAHs and in other hospitals, particularly those located in communities with severe shortages of physicians and non-physician practitioners (NPPs), has been, out of necessity, furnishing therapeutic services under the *general supervision* of a physician or a qualified NPP. For CAHs, this approach is consistent with their Medicare conditions of participation (CoPs) at 42 CFR 485.631 and 42 CFR 485.618 that allow these facilities to operate with reduced staffing levels as a trade-off for local access to hospital-level care.

There are several problems with CMS' proposed hybrid supervision policy. First, the level of supervision required for the "initiation" of these 16 services is direct supervision. For practical purposes, this means that a physician or NPP must be present in the hospital and immediately available at all times these services are available to the community both during and after normal business hours. In fact, all 16 of the services included in CMS' list of "nonsurgical extended duration therapeutic services" are typically provided by hospitals and CAHs 24 hours a day, 7 days a week (24/7). Thus, a physician or NPP must be present in the CAH at all times in case a patient presents requiring any of these services. While in some CAHs and rural hospitals an emergency physician could provide this 24/7 level of supervisory presence, the ambiguity in CMS' policy regarding whether an emergency physician is truly "immediately available" and also "clinically appropriate" to supervise a wide range of outpatient services, makes this a tenuous solution at best. **If these 16 services truly have a low risk of complication after initial assessment, and if, as is currently the case with CAHs, such an assessment can be made by trained qualified ancillary staff who are directly communicating with an on-call physician or NPP by telephone, radio or other means, the AHA contends that these services, in their entirety, should be permitted to be provided under the *general supervision* of a physician or NPP.**

We also are concerned that CMS' proposed policy could subject supervising physicians and NPPs to untenable levels of enforcement scrutiny regarding the clinical appropriateness of their decisions to move patients from direct to general supervision upon completion of the "initiation" phase of a service on the list. While we agree that the determination that a patient is sufficiently

stable to transfer from direct to general supervision and the timing of that decision should not be defined by CMS policy, but left to a physician's or NPP's clinical judgment, the policy itself is ripe with opportunities for CMS' contractors, such as recovery audit contractors, to second-guess the clinical judgment of the supervising physician or NPP. Moreover, the requirement to document this point of transfer from direct to general supervision would be burdensome and only add to the mountains of paperwork already required of physicians, without contributing to patient safety or quality of care.

Also, and most importantly, the list of services subject to a reduced level of supervision is too limited. There are numerous other outpatient therapeutic services that are covered by Medicare, including additional extended duration services, certain short duration services, certain minor surgical procedures and the recovery portion of certain surgical services, which could be provided safely under general supervision.

To help identify some of these services, the AHA asked a group of physician leaders from a hospital system to review a subset of Medicare covered outpatient therapeutic services that are paid under both the OPPS and the physician fee schedule (PFS) and for which the PFS assigns a low physician relative work value (less than 1.0 RVUw). The group was asked to identify those procedures that, in their judgment, were of such low complexity and low risk that they could be furnished under the general supervision of a physician. The physicians easily identified more than 160 procedures that met these criteria. While the list includes some of the same extended duration services that CMS has proposed for a reduced level of supervision, there also was a number of additional extended duration services identified as being appropriate for general supervision, such as, CPT 36430 (Blood transfusion service), CPT 96413 (Chemotherapy, IV infusion, 1 hour), and CPT 90853 (Group psychotherapy). The physicians also identified a number of commonly provided short duration services – CPT 90471 (Immunization administration), CPT 51702 (Insert temporary bladder catheter) and CPT 97602 (Wound(s) care, non-selective) ─ that they believe could be furnished safely under general supervision.

The AHA also disagrees with CMS' decision to exclude all surgical services, including the recovery period of certain surgeries, from consideration for a reduced level of supervision. In the proposed rule CMS does not explain its rationale for excluding all surgical services from consideration. We believe that there may be many low-risk, minor surgical procedures that could be performed safely under general supervision in a hospital outpatient department. Further, CMS does not adequately explain why it is excluding the surgical recovery period from consideration. The agency only states, "although monitoring of any patient in recovery is a key component of surgery, it is not the focus or a substantial component of the service and because we believe the surgeon should personally evaluate the patient's medical status during the recovery period." The AHA agrees that a surgeon and, as appropriate, an anesthesiologist or a certified registered nurse anesthetist, should evaluate the patient's medical status for some portion of the surgical recovery period. However, 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.

A New Approach is Needed for the Supervision of Outpatient Therapeutic Services
Despite the marginal changes CMS made in the 2010 supervision policy and those CMS is proposing for 2011, hospitals and CAHs remain concerned about the implications of the agency's burdensome, unnecessary and short-sighted policies. Continuing to fine-tune this ultimately unworkable and unwarranted policy through frequent sub-regulatory reinterpretation and annually through minor regulatory changes is not appropriate. Hospitals, CAHs and the patients they serve deserve a policy that is comprehensive, stable, based on clinical input and data, and ensures ongoing access to high-quality patient care. In the paragraphs below we describe why the current CMS policy is not working and why our vision for a more comprehensive policy should be adopted.

CMS' supervision policy is unwarranted. CMS offers no real clinical or quality basis for its new and burdensome supervision requirements. In fact, the agency has presented no evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision.

Hospital outpatient therapeutic services have always been provided with the highest quality of care principles in mind. These services are ordered by the patient's treating physician, who is responsible for assessing the patient's progress and, when necessary, changing the treatment regimen. Many services are furnished in the hospital outpatient department by licensed, skilled professionals under the overall direction of a physician or a NPP.

For many low-risk and low-complexity services, a physician does not need to be physically present in order for hospital staff to provide safe, high-quality outpatient care. This is because non-physician hospital staff are competent, licensed health care professionals who provide services that fall within their scope of practice in accordance with state law. Further, the provision of care is governed by clinical protocols, policies and procedures that are approved by the hospital's medical staff. Non-physician staff can contact a physician by phone, radio or other means if needed for routine consultation. In CAHs, non-physician staff, such as nurses, are trained differently in order to support their ability to provide high-quality and safe care in an environment in which there is less face-to-face contact with physicians and a greater dependence on clinical protocols, policies and procedures.

Should an unforeseen situation arise, medical staff physicians can be promptly summoned. The Joint Commission's National Patient Safety Goals state that rapid response teams are to be in place to provide assistance. If a patient emergency arises, the rapid response team, including a physician, is available to provide care.

Due to continuing shortages of physicians and NPPs, many hospitals and CAHs are finding it difficult, if not impossible, to meet CMS' supervision requirements. There are inadequate numbers of physicians and other NPPs available to provide direct supervision, particularly in rural areas. Therefore, the marginal additional flexibility CMS provided in the 2010 OPPS final rule to permit certain NPPs to provide direct supervision for outpatient therapeutic services does not go far enough. Moreover, CMS' added flexibility would not apply to certain outpatient

services, such as cardiac and pulmonary rehabilitation and certain diagnostic services, which CMS states may be supervised only by a physician. A shortage of physicians and NPPs in rural and other communities dilutes the utility of CMS' more flexible policy.

Additionally, as noted earlier, CMS' proposed policy for 2011 fails to adequately address the concerns that hospitals and CAHs have raised. The proposal would apply only to a small set of services, still require direct supervision by a physician or NPP for the initiation portion of these services, and subject the supervising professional to additional enforcement scrutiny.

CMS' requirements are overly restrictive. CMS' supervision requirements severely restrict the ability of hospitals and CAHs to effectively use their existing staff to make supervisory assignments and leave them with limited options to comply.

For instance, although CMS asserts that its requirements may be met by assigning the responsibility for direct supervision to a physician of a different specialty from the services being supervised or to a NPP, the details of CMS' policy effectively eliminates a hospital's or CAH's ability to do so. This is because CMS also requires that the supervising professional be authorized to actually provide the service he/she is supervising, according to his/her state license and hospital-granted privileges. Thus, for all practical purposes, for many services the supervising professional must in fact be a physician or NPP of the same specialty as the service being furnished. This requirement is impractical, if not impossible, for many small and rural hospitals and CAHs to meet, due to severe shortages of specialist physicians and NPPs in the community.

In addition, CMS' requirement that the supervising physician or NPP be "immediately available" to furnish assistance and direction throughout the performance of the procedure negates the marginal change CMS made in CY 2010 to allow the supervising professional to be present anywhere on the same hospital campus. The requirement for immediate availability means that the supervising professional cannot be engaged in any other activity that cannot be interrupted at a moment's notice. In effect, the supervising physician or NPP must be on-site at all times outpatient services are being furnished by hospital professionals, unoccupied by other responsibilities, and waiting for the unlikely circumstance in which he/she will be called upon to assist.

Even CMS' claim that it has provided some additional flexibility to CAHs and small and rural hospitals by allowing emergency physicians to directly supervise outpatient services falls victim to these "catches" in CMS' policy. That is, while emergency physicians may supervise, they can do so only if they meet the other requirements of direct supervision, such as being immediately available (i.e., they must be able to be interrupted to furnish assistance and direction in the delivery of therapeutic services provided elsewhere in the hospital) and able, under their license and hospital-granted privileges, to step in and take over the furnishing of the broad range of therapeutic services that are typically offered in hospital outpatient departments.

Even if physicians or NPPs of various specialties are present in a community, they are unlikely to abandon their private practices in order to do nothing other than supervise hospital outpatient services. Further, in the current economic climate and with competing patient care and other operational priorities, it is infeasible for hospitals and CAHs to hire a group of hospital-privileged specialist physicians and NPPs for the sole purpose of being "immediately available" around the clock to supervise various hospital outpatient therapeutic services. Ensuring compliance forces hospitals and CAHs to consider eliminating certain services or reducing their hours of operation.

The compliance choices for CAHs, which are located in remote areas plagued by severe shortages of physicians and NPPs, are especially difficult. CAHs are subject to several co-existing and contradictory Medicare regulations that are forcing vulnerable facilities into an untenable dilemma which, for many, threatens their continued ability to provide care to Medicare beneficiaries in their community.

On one hand, CAHs are permitted, through their Medicare CoPs, to operate under a lower level of staffing than other hospitals. In this proposed rule, CMS has described the Medicare CoPs as "minimum standards for patient health and safety…. focus[ed] on creating a foundation to ensure quality and safe care for beneficiaries throughout a given facility, irrespective of the payment system or service provided." The CAH CoP at 42 CFR 485.631 requires a physician or NPP to be available by phone, but not necessarily physically present on the CAH campus. In order to ensure access to hospital emergency care in these otherwise underserved areas, the CAH CoP at 42 CFR 485.618, has long required only that a physician or NPP be able to arrive within 30 minutes of a request from the staff in the facility.

On the other hand, the "incident to" regulation from which the direct supervision requirement emerges, is not explicitly related to health and safety, but rather sets forth the conditions under which Medicare will cover and pay for outpatient hospital services. As noted earlier, due to severe health professional shortages in many communities in which CAHs exist, finding a physician or NPP who can be present and immediately available, in the hospital or on its campus at all times services are furnished to Medicare beneficiaries, as compliance with the direct supervision rule requires, is impossible.

Therefore, a CAH may be in full compliance with CMS' long-standing CoP health and safety standards, which allows physicians and NPPs to be available by phone and permits 30 minutes for the on-call physician or NPP to respond in an emergency, but it would, nonetheless, be forced to forgo payment for the life-saving services furnished due to its inability to have a physician or NPP on-site 24/7. For example, if a patient comes to the CAH's ED with a serious injury or illness, in most cases, the CAH staff would examine the patient and contact the on-call physician or NPP for orders. For serious emergencies, the CAH staff would not wait until the on-call physician arrives to begin providing critical services. To do otherwise would pose a dangerous risk to patient safety and quality of care. However, under the direct supervision policy, any life-saving emergency services furnished to the patient before the

physician or NPP physically arrives in the ED would be considered to be "not reasonable and necessary" and would not be covered by Medicare.

In addition, for the many low-risk and low-complexity therapeutic services furnished in CAH outpatient departments this disconnect between the CoPs, which are intended to enable access to hospital-level outpatient care in underserved areas and the payment coverage requirements, which mandate costly and unnecessary direct supervision, likely results in an increased cost of care without improving patient safety or quality.

The AHA's Proposal

CMS needs to make a fundamental change in its supervision policy. A more comprehensive and clinically-based approach is needed for assigning levels of physician supervision to outpatient therapeutic services. Medicare covers and pays for outpatient therapeutic hospital services as services furnished "incident to" a physician's service, as described in *Social Security Act* §1861(s)(2)(B). The law does not mandate a specific level of physician supervision for "incident to" services. CMS possesses the regulatory discretion to determine the appropriate level of supervision for these services.

The AHA recommends that CMS adopt a default standard of "general supervision" for outpatient therapeutic services. However, because we recognize there are high-risk and complex services furnished in hospital outpatient departments that would benefit from a higher level of supervision, an exceptions process should be established to identify specific procedures that should be subject to direct supervision. Such an exceptions process should involve recommendations from a clinical expert panel composed of physicians and NPPs who practice in hospital outpatient departments in urban and rural communities, including CAHs, and whose specialties reflect the range of services covered by Medicare in hospital outpatient departments. Further, to ensure full and appropriate consideration for the services recommended for designation as requiring direct supervision, the recommendations from the clinical expert panel should be subject to notice and comment through a public rulemaking process.

A special rule should be established for CAHs in recognition of their unique personnel CoPs. In order to allow CAHs to continue to furnish a wide range of services to their communities, including those outpatient therapeutic services determined through the exceptions process to require direct supervision, CAHs should be considered to be in compliance with the direct supervision requirements for a service if they comply with the CoP standard for personnel required under 42 CFR 485.618. That is, when a service requiring direct supervision is furnished in a CAH, the on-call supervising physician or NPP arrives at the CAH within 30 minutes of being called.

The AHA recommends that CMS revise the definition of "direct supervision" for outpatient therapeutic services furnished in hospitals and in on-campus and off-campus provider-based departments to allow physicians and NPPs to be "immediately available" in ways other than just appearing in person. With this Administration's focus on advancing the applications of technology in health care, including telemedicine and robotic technologies for

health care delivery, we recommend that direct supervision explicitly include, as appropriate, response via radio or telephone, or through other technologies approved for use in Medicare, such as telemedicine.

The AHA recommends that CMS revise the definition of "direct supervision" for outpatient therapeutic services furnished in an off-campus provider-based department to allow the supervising professional to be present in the department or "in close proximity" to the department. Many hospitals place their off-campus provider-based departments in medical office buildings that also house the private physician practices from which supervising physicians are drawn. Under the 2010 direct supervision policy, a physician located in a private office in a suite adjacent to the hospital's off-campus provider-based department would not be in compliance with the requirements for direct supervision, despite being "immediately available", because he/she is not physically present in the hospital outpatient department when the outpatient therapeutic services are furnished.

We recognize that a more reasonable and comprehensive supervision policy, as described above, will take at least a year to establish and implement, and, in the meantime, many CAHs and other small and rural PPS hospitals will remain unable to comply with the requirements of the direct supervision regulations. **Therefore, the AHA also recommends that CMS extend through CY 2011 the enforcement moratorium that is currently in place for CAHs and also apply the moratorium to other small and rural PPS hospitals. Small and rural PPS hospitals located in communities that are experiencing health professional shortages are particularly challenged.** As CMS notes in the proposed rule, its decision not to enforce the rules for supervision of hospital outpatient therapeutic procedures furnished in CAHs in CY 2010 was in response to rising concerns among the rural community about the rules and the inability of hospitals to meet the direct supervision requirements. As we describe above, CMS' proposed "hybrid" supervision policy for 16 services will not provide much assistance to CAHs or other small hospitals. While the AHA's preferred approach would enable CAHs and other hospitals to continue to provide access to covered outpatient services, especially in medically underserved areas, given the lead time for putting the new system into place additional relief is necessary for CAHs and other small and rural PPS hospitals.

CANCER HOSPITAL ADJUSTMENT

There are 11 cancer hospitals in the United State 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. However these temporary TOPs expire on December 31, 2010. The federal TOPs made to cancer hospitals are substantial, with cancer hospitals receiving about $164 million, (or nearly 80 percent of the total $206 million in TOPs, according to hospital

cost report data. While these hold-harmless payments are set to expire for other hospitals at the end of this year, cancer hospitals remain permanently eligible.

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 ambulatory payment classification (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 much higher than the standardized cost per discounted unit of all other hospitals, and,
- cancer hospitals' volume weighted average payment-to-cost ratio (PCR) is significantly 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, 0.615) and the weighted average PCR of other hospitals paid under the OPPS (0.868). CMS estimates that this proposed adjustment would result in aggregate increases in OPPS payments to cancer hospitals of 41.2 percent for 2011. In order to meet congressional requirements for budget neutrality, CMS proposes to reduce payment to all other hospitals by 0.7 percent, or $280 million.

CMS notes that as a result of this proposed adjustment, it expects that only one of the 11 cancer hospitals will receive TOPs in 2011. That is, because the agency 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 is proposing to eliminate its obligation for making "hold harmless" TOPs, and instead, shifting this financial burden to all other hospitals.

The AHA supports appropriate payment for cancer hospitals; however, we do not believe that CMS' proposed cancer hospital adjustment is consistent with congressional intent nor can it be considered "appropriate" due 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. <u>We urge CMS to consider TOPs in its methodology for calculating the cancer hospital adjustment</u>.

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' 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' 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 did not consider TOPs in assessing costliness of cancer hospitals relative to other hospitals furnishing OPPS services because "section 3138 of the Accountable Care Act 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' 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' proposed cancer hospital adjustment is not made in a budget-neutral manner; it actually reduces federal expenditures significantly by eliminating TOPs for 10 of the 11 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 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, 0.83) and the OPPS PCR for other hospitals (0.868). 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 should result in more of the cancer hospitals remaining eligible to receive TOPs for 2011 than would be the case under CMS' proposal.

In addition, because there is an inverse relationship between increases in APC payments and the amount that cancer hospital receive in TOPs payments, **the AHA also strongly recommends that CMS not include the cancer hospital adjustment amount, or the related increases in beneficiary copayments, in calculating these hospitals' eligibility for TOPs or for calculating the amount of the TOPs payments during cost report**

settlement. Cancer hospitals should not be penalized for receiving these adjustments intended to improve payment equity.

CMS also proposes to recalibrate the "other hospital" PCR target amount and the hospital-specific percentage adjustment for each cancer hospital periodically, but not every year, indicating that the agency does not believe that these amounts will change so drastically in any given year to warrant annual recalculation. **The AHA disagrees and urges CMS to annually recalibrate the "other hospital" PCR target as well as the hospital-specific percentage adjustment.** We believe that the large budget neutrality adjustment applied to non-cancer hospitals will cause the "other hospital" PCR to decline significantly in 2011 and subsequent years, particularly if CMS does not accept the AHA's recommendation on its methodology. It would be unfair to impose a larger than necessary budget neutrality adjustment to non-cancer hospitals due to a too high "other hospital" PCR target used in future cancer hospital adjustments. Annual recalibration would ensure more equitable payments.

OUTPATIENT PPS: QUALITY DATA

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

A Vision for Reporting Quality Measures

In the proposed rule, CMS outlined a three-year implementation plan for quality measures, thus, proposing a longer term vision for the outpatient quality reporting program. While we applaud CMS' intention of providing greater predictability about the measures to be used in future years, we are concerned that this extended plan lacks a unified framework with clearly articulated goals of what CMS would like the outpatient reporting program to achieve. The proposal also fails to take into account important aspects of the ACA. The law clearly promotes greater integration of care across the delivery system. And, CMS' approach to measuring care for patients in the hospital inpatient and outpatient settings could begin to build an important framework for assessing care across the continuum. However, the proposal makes no mention of how the outpatient reporting program could work in concert with the inpatient program to portray a holistic picture of quality across the continuum of hospital care.

We urge CMS to build 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 Partners' national priorities is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The Hospital Quality Alliance (HQA) agrees that the Partners' national goals should provide a foundation for its future work, and it would be beneficial for CMS to follow these national goals as well.

Once an overarching framework is identified, it is critical that meaningful measures be selected for implementation. Public reporting of the measures on *Hospital Compare* leads to a 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. To do this, CMS should follow a clear set of criteria to determine which measures are most scientifically sound. We suggest that CMS look to criteria recently developed by The Joint Commission. The Joint Commission has spent time examining what makes some measures better than others and concluded that excellent measures are measures:

- for which there is a large volume of research linking the measure to improved outcomes;
- that accurately assess whether evidence-based care has been delivered;
- that address a process that is close in proximity to the desired outcome; and
- for which implementation has minimal unintended adverse consequences.

The AHA agrees with these criteria. Further, we urge CMS not to adopt measures that are not NQF-endorsed and HQA-adopted as these two organizations have standing processes in place to evaluate measures against those criteria articulated by The Joint Commission. The NQF process identifies those measures that accurately assess relevant clinical processes, and both the HQA and the NQF processes help identify those measures that have an important linkage to improved clinical outcomes and have minimal unintended consequences. Our specific comments on the measures proposed for 2012 through 2014 are outlined below.

Quality Measures for 2012

We remained 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 it 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.

Further, CMS' 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 retire these measures from the outpatient pay-for-reporting program.

For 2012, CMS has proposed the addition of six measures, including one measure on the use of health information technology (HIT), four new measures of imaging efficiency, and one additional measure of emergency department (ED) heart attack care.

The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program. This measure assesses HIT functionality and does not directly address the quality of the care provided. Measures that address HIT functionality should remain in the meaningful use HIT functionality objectives for the Medicare electronic health record (EHR) incentives program; they should not be included as quality measures in the pay-for-reporting programs. This measure is similar, but not identical, to the meaningful use functionality objective to incorporate structured clinical-lab data into the EHR. We believe asking hospitals to report on two similar but not identical measures for the outpatient reporting program and the meaningful use criteria is duplicative, redundant and burdensome.

In the meaningful use final rule, CMS stated that it has fulfilled the statutory requirement in the HITECH Act to avoid redundant and duplicative reporting because none of the meaningful use clinical quality measures are used in the Medicare pay-for-reporting programs. However, the proposal of this outpatient measure introduces redundancy and additional confusion as the two measures are not identical. In addition, the related functionality measure is one that is included among the optional "menu set" objectives for the EHR incentives program. It is inappropriate for CMS to make an "optional" functionality measure a <u>required</u> quality measure. The AHA encourages CMS to coordinate internally on how HIT is utilized.

Preoperative Evaluation for Low-Risk Non-cardiac Surgery Risk Assessment – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program. We are concerned that there is no known benchmark for the appropriate rate of single photon emission computed tomography myocardial perfusion imaging (SPECT MPI) and stress echocardiography among the measure population of patients receiving low-risk, non-cardiac outpatient surgeries. One study at the Mayo Clinic in Rochester, Minnesota found that 14 percent of SPECT MPI procedures were considered inappropriate using criteria published by the American College of Cardiology Foundation and the American Society of Nuclear Cardiology. However, this study did not assess the patient population that is specific to this measure. Therefore, without a clear evidence-based benchmark, providers cannot use the measure for quality improvement purposes. The measure also has no value to patients making decisions about their care, as it is difficult to interpret each provider's rate in the absence of an evidence-based benchmark. The absence of a clear benchmark is one of the principal challenges faced by the imaging efficiency measures currently included in the outpatient reporting program. We urge CMS not to repeat the mistake of including measures that lack clear goals for quality improvement.

In addition, this measure assesses only whether an imaging procedure was conducted within 30 days prior to the patient's surgery. The measure does not capture the reason why the imaging procedure was performed. Thus, there is the potential that appropriately performed procedures could be misclassified into the numerator of the measure. However, there is another measure addressing this topic also proceeding through NQF review at this time. The AHA believes that this measure, "Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low-risk surgery patients," is a more appropriate measure than the one proposed by CMS. This alternate measure uses medical chart review to determine the proportion of inappropriate imaging procedures performed out of all imaging procedures conducted at the facility. We recommend that CMS examine this measure more closely and propose it in next year's outpatient PPS proposed rule.

Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI Post Coronary Artery Bypass Graft (CABG) – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program. In fact, the NQF Steering Committee decided not to bring the measure forward for endorsement because it contained numerous methodological shortfalls.

Simultaneous Use of Brain Computed Tomography and Sinus Computed Tomography – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program. This measure has not been recommended for NQF endorsement by the NQF Steering Committee currently reviewing the measure. In its decision not to bring the measure forward for endorsement, the Steering Committee noted that the measure did not target a procedure with a high magnitude of overutilization. According to the materials CMS presented to the NQF, only five percent of patients who received a brain CT also received a sinus CT on the same day. Among those five percent of patients, it is unknown how many of the scans could be considered inappropriate.

Use of Brain Computed Tomography in the ED for Atraumatic Headache – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program as it has not been recommended for NQF endorsement by the NQF Steering Committee currently reviewing the measure.

Troponin Results for ED Acute Myocardial Infarction (AMI) Patients or Chest Pain Patients (with Probable Cardiac Chest Pain) Received within 60 Minutes of Arrival – The AHA is pleased that this measure supplements the existing measure set of heart attack/chest pain care for ED patients who are transferred to other hospitals for advanced cardiac care. The AHA has long advocated for measures to be added in measure sets around a particular condition or group of patients. Measure sets provide a more comprehensive picture of care and lessen the reporting burden on hospitals because each individual measure adds only a few unique data elements to the sum of information that must be collected by hospitals. However, we are unsure whether this measure is appropriate for those hospitals that transfer heart attack/chest pain patients who present in their EDs. Hospitals that transfer patients are likely to be smaller and have less access to updated technology and fewer staffing resources. Some small hospitals do not have laboratory staff on-site 24 hours a day. In those facilities, if a heart attack patient came to the ED in the

middle of the night, the hospital would have to bring the on-call laboratory personnel to the hospital and allow time for the equipment to be calibrated before the test could be performed. In such instances, it would likely be much more appropriate for the patient to be stabilized and then transferred as quickly as possible to another facility for further care.

We are concerned that this measure could have the unintended consequence of inadvertently directing hospitals to hold patients in their EDs for longer than necessary in order to run the troponin test and fulfill this quality measure. We suggest that before finalizing this measure in the outpatient reporting program, CMS should perform extensive field testing of this measure in small, rural hospitals to assess its applicability and test for any unintended consequences.

In addition, we are concerned that this measure may not truly capture whether high-quality, evidence-based, efficient care has been delivered. The measure would be improved if it measured whether the appropriate treatment was administered following the timely receipt of test results, rather than simply the timing of when the test results were returned.

Quality Measures for 2013

For 2013, CMS has proposed the addition of seven measures, including one measure on the use of HIT, one measure of care coordination, four measures of ED efficiency, and one measure of imaging efficiency.

Tracking Clinical Results between Visits – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program. As we stated above, measures that address HIT functionality should remain only in the meaningful use HIT functionality objectives.

Transition Record with Specified Data Elements Received by Discharged Patient – The AHA supports the inclusion of this measure into the outpatient pay-for-reporting program after the measure has been fully field-tested and the results of the testing show that hospitals can collect the data in a consistent manner. Hospitals are working hard to provide thorough communication to patients when they leave the ED to ensure that patients have the information they need to receive appropriate follow-up care. This measure, which is scientifically valid and well-specified, will give hospitals a tool to see how well they are doing at providing this information. We look forward to further measure development in this area to gain a better understanding of how well patients understand their instructions for follow-up care and are able to receive that care in a timely manner.

Median Time from ED Arrival to ED Departure for Discharged ED Patients – The AHA does not support the inclusion of this measure into the outpatient pay-for-reporting program. As structured, this measure includes the time spent while patients are actively receiving care, in addition to the time spent waiting in the ED. We believe the *Door to Diagnostic Evaluation by a Qualified Medical Professional* (see below for a discussion) is a more appropriate measure to determine ED efficiency and throughput. We also note that the field-testing of this measure has found challenges with hospitals' ability to capture the ED arrival time data element in a way that is comparable across different facilities.

Door to Diagnostic Evaluation by a Qualified Medical Professional – The AHA supports the inclusion of this measure into the outpatient pay-for-reporting program if the definition of "qualified medical professional" is expanded and the measure has been fully field-tested and the results of the testing show that hospitals can collect the data in a consistent manner. This measure examines the length of time between a patient's presentation to the ED and the time that the patient is first seen by a provider. The technical specifications for this measure define a provider as a person who can "initiate a diagnostic evaluation or therapeutic plan," such as a physician, advanced practice nurse, resident or medical student. Registered nurses are excluded from this definition. We have concerns that these specifications could place some hospitals at a disadvantage to performing well at this measure. Hospitals staff their EDs in many different ways. In particular, to address overcrowding and patient flow issues, some hospitals have developed creative and flexible approaches to provide timely care to patients using all appropriate staff. We are concerned that, as currently structured, this measure could stifle innovation in ED staffing by measuring hospitals on the time it takes for a patient to reach only a subset of all of the staff that provide care to patients in EDs.

ED – Median Time to Pain Management for Long Bone Fracture – The AHA is concerned that this measure is the only measure put forward regarding pain management in the ED setting. Again, the AHA is a proponent of measures to be added in measure sets around a particular condition or group of patients as this approach provides a more complete picture of care.

ED – Patient Left before Being Seen – The AHA supports the inclusion of this measure into the outpatient pay-for-reporting program after the measure has been fully field-tested and the results of the testing show that hospitals can collect the data in a consistent manner. The measure appears to be scientifically valid and can provide valuable information to hospitals in assessing their ability to provide care to all patients in their EDs in a timely manner; however, we understand that early testing of this measure has shown hospitals have encountered difficulties in collecting the relevant information.

ED – Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Who Received Head CT Scan Interpretation within 45 Minutes of Arrival – The AHA agrees that this measure addresses a topic for which an opportunity for improvement exists. The measure appears to be thoroughly developed and well-specified and aligns with national stroke guidelines; however, it has not yet been field-tested. Before it is implemented in the outpatient pay-for-reporting program, the measure should be fully field-tested to show that hospitals can collect the data in a consistent manner. In particular, we believe that hospitals will find it challenging to consistently collect the information necessary to determine whether patients are arriving at the ED within two hours of the onset of symptoms, as well as collect the information on the timing of when the scan was interpreted.

We also are concerned that this measure is the only measure put forward regarding ED stroke care. The AHA has long advocated for measures to be added in measure sets around a particular condition or group of patients. We suggest that CMS look to the set of stroke care measures

previously endorsed by the NQF and harmonize the measure specifications for this measure to those of the previously endorsed measures wherever possible.

Quality Measures for 2014
For 2014, CMS has proposed the addition of six measures, including five new measures of diabetes care and one measure of imaging efficiency.

Measures of Diabetes Care: Hemoglobin A1c Poor Control in Diabetic Patients; Low Density Lipoprotein Control in Diabetic Patients; High Blood Pressure Control in Diabetic Patients; Dilated Eye Exam in Diabetic Patients; Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients – These measures are well-developed and well-tested, but they were developed and specified for use in the physician office setting. While they may be appropriate for use in the hospital outpatient setting as well, significant barriers to implementation exist, and the measures need to be refined for and tested in the hospital outpatient setting. The identification of the appropriate patient population within each facility will be a challenge. It is unclear whether CMS intends for the measure population to include all patients with diabetes who receive outpatient care at the hospital or just those patients coming to the hospital specifically for ongoing primary care for their diabetes. Including all diabetes patients in the measure population would be unduly burdensome and illogical. It also would lead to tremendous variation in the applicable patient populations across hospitals. Some hospitals have provider-based clinics that are paid under the outpatient PPS and are a source of primary care and other outpatient services in their communities. However, the types of clinics and the types of patients cared for in each clinic varies widely among hospitals. In addition, the patient populations served by hospitals that have clinics are different from the patient populations at hospitals without clinics.

CMS needs to provide additional specifications to identify the appropriate patient population for this measure. Further, the diabetes measures are specified to follow patients over a period of time. Much of the care provided in the hospital outpatient setting is episodic and fragmented. Even hospitals with clinics may have very small patient populations who receive care over the entire measure timeframe.

Exposure Time Reported for Procedures Using Floroscopy – The AHA believes this measure is an important metric of imaging care in the hospital outpatient setting. However, the measure is currently specified for collection in the physician office setting using CPT Level II codes. As hospitals do not report CPT Level II codes on their claims, more work will be needed to make this measure appropriate for use in the hospital outpatient setting.

Program Procedures
In the proposed rule, CMS states that hospitals would be required to submit their outpatient measure population and sample size data. For the past several years, the submission of this information has been voluntary, as CMS has recognized that collecting this information is both burdensome and time-consuming for hospitals. We believe that identifying this information continues to be burdensome, and we urge CMS not to finalize the provision in the final rule. The

challenges to do this are particularly great for both larger hospitals with very large patient populations and for hospitals with less integrated HIT systems.

Data Validation for 2012 and Subsequent Years
CMS proposes a new process for validating hospitals' outpatient quality data beginning in 2012. Under the proposal, CMS would review 48 medical charts (12 per quarter) from 800 randomly selected hospitals each year. The review would assess the accuracy of each hospital's measure rate, reflecting whether or not the hospital classified patients appropriately into the measure denominators and numerators. **The AHA believes that CMS' proposed process holds promise as a reasonable approach to ensure the accuracy of the quality data.**

We support CMS' focus on the hospital's measure rate, as opposed to individual data elements, because the measure rate captures the information that is truly important to patient care. For data validation in the inpatient reporting program, there have been several instances in which a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, have caused hospitals to fail validation. Validating the hospital's measure rate should eliminate these unfortunate incidents.

We also agree with CMS' proposal that to pass validation hospitals must meet a minimum of 75 percent reliability from chart validation.

PAYMENT FOR OUTPATIENT DRUGS

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. In 2011, 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 current 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 2011, 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 biologics, arriving at a proposed rate of ASP plus 6 percent – the rate that the AHA has recommended for several years. This is higher than the ASP plus 4 percent rate paid in 2010. 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 resulted in a payment rate of ASP plus 0 percent. Then, CMS made a payment adjustment that redistributes pharmacy overhead costs, in the amount of $200 million, from packaged drugs to separately payable drugs. The $200 million consists of $150 million from the coded packaged drug cost for drugs with an ASP and $50 million from the packaged drug cost for drugs without an ASP. This boosts the proposed payment rate for separately payable drugs to ASP plus 6 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 25 percent and the cost of packaged drugs and biologicals without a HCPCS code or an ASP by 8 percent.

In explaining its decision to continue to redistribute $150 million of the pharmacy overhead from packaged drugs with an ASP to separately payable drugs, CMS describes analyses it conducted that support its assumption that between one-third and one-half of the $483 million in pharmacy overhead cost currently associated with coded packaged drugs and biologicals is misapplied, as a function of both charge compression and the agency's choice of an annual drug packaging threshold. In addition, in redistributing $50 million, or 8 percent of the total cost of uncoded packaged drugs and biologicals, CMS makes the conservative assumption that whatever pharmacy overhead cost is not accurately associated with uncoded packaged drugs, it would not be less than 8 percent of total uncoded drug costs. Based on these analyses, CMS claims its payment methodology offers a more appropriate allocation of pharmacy overhead cost to separately payable drugs and biologicals.

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' recognition of flaws in its previous rate-setting methodology and the fact that the SCOD payment rate that CMS proposes, ASP plus 6 percent, is serendipitously consistent with the payment rate that the AHA previously recommended; however, we are concerned that when CMS uses more updated data to calculate the final ASP plus X percent payment rate for SCODs, it could be lower than what has been proposed. As stated earlier, rates below ASP plus 6 percent are 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 lesser rate, while maintaining drug payments at ASP plus 6 percent for drugs provided in physician offices, creates payment inconsistencies that could lead to 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.

Further, CMS' methodology is unstable. That is, the resulting ASP plus X percent payment amount is extremely sensitive to even relatively minor changes in calculations, assumptions or overhead allocation methodologies. For example, CMS' methodology incorporates data from hospitals that participate in the 340B drug discount program, which allows certain hospitals that serve poor and uninsured patients to purchase drugs at deeply discounted prices. When CMS compares its estimated mean unit costs to ASP to determine a payment rate for all hospitals, it includes hospitals that purchase drugs under the 340B program in its analysis, although the 340B sales are excluded from the ASP calculation. As a result, CMS underestimates the aggregate costs of drugs for most hospitals, and the ASP-based rate that CMS produces by comparing aggregate costs to ASP is too low. The 340B program was not intended to harm other hospitals' ability to provide care by reducing their Medicare reimbursement, and the AHA would strongly oppose Medicare paying 340B hospitals a separate rate based on their claims data alone. However, it is important to note that the inclusion of data from 340B hospitals will pose a growing problem for calculating appropriate rates for separately payable drugs under CMS' current methodology because the numbers of 340B participating hospital sites has increased dramatically over the last several years and will grow further due to provisions in the ACA that expand the 340B program.

Due to the instability in CMS' 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 (or the CAP rate, as applicable.)

Cost Reporting Policy for HCPCS-coded Drugs

In the proposed rule, CMS states, "We also note that, although it is CMS' longstanding policy under the OPPS to refrain from instructing hospitals on the appropriate revenue code to use to charge for specific services, we continue to encourage hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged. *We believe that a practice of billing all drugs and biologicals with HCPCS codes under revenue code 0636 (Pharmacy – Extension of 025X; Drugs Requiring Detailed Coding) would be consistent with NUBC billing guidelines and would provide us with the most complete and detailed information for ratesetting* [Emphasis added]. We note that we make packaging determinations for drugs annually based on cost information reported under HCPCS codes, and the OPPS ratesetting is best served when hospitals report charges for all items and services with HCPCS codes when they are available, whether or not Medicare makes separate payment for the items and services."

Due to concerns raised by hospitals regarding these statements, the AHA asked the chairman of the National Uniform Billing Committee (NUBC) to comment on CMS' assertion that *all* drugs and biologicals with HCPCS codes should be billed under the 0636 revenue code. In NUBC

discussions on August 11, CMS was asked to explain their position. The agency indicated that it did not intend for all drugs with a HCPCS code to be reported under the 0636 revenue code. This being the case, the NUBC noted that the current OPPS statement is confusing for hospitals, and that CMS should clarify that the original intent of the 0636 revenue code was to capture those drugs for which a health plan requires special tracking – such as for costly cancer drugs. The NUBC noted that other revenue code categories, such as revenue codes 025x as well as the 063x that have HCPCS noted as a reporting component, should continue to be used along with their respective HCPCS codes. The NUBC noted that the continuation of the 025x and 063x would allow CMS and providers to create better cost-to-charge ratios. **Consistent with these comments, the AHA recommends that CMS clarify these issues in the final rule in order to avoid any further confusion for hospitals.**

The NUBC also noted that there are drugs that do not have a specific revenue code, such as aspirin, and that for these drugs there is a designated HCPCS code for "unspecified drugs" that could be used. The NUBC did not at this time make a recommendation on whether unspecified drugs should have a distinct revenue code created. **The AHA agrees with the NUBC recommendation that CMS comment in the final OPPS rule as to whether the agency would find it beneficial to have a new revenue code for the unspecified drugs and whether these should be captured on a different line item on the cost report.**

PROPOSED OPPS PAYMENT FOR DRUG ADMINISTRATION

As part of its standard annual review, CMS analyzed the assignments of drug administration CPT codes into the five-level APC structure. Based on the results of this review, CMS proposes to continue to pay separately for the same set of drug administration codes under the 2011 OPPS as were paid separately in 2010. The AHA recommends that CMS continue to evaluate the five-level APC structure on a yearly basis.

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 emergency department (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 comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience.

For 2011, 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, patient complexity or severity, and therefore, each hospital's reported E/M levels reflect a different aspect 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 has just been 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' apparent lack of interest in adopting national guidelines, the AHA urges CMS to support a request to the AMA CPT Editorial Panel to 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.

OUTPATIENT PPS: PARTIAL HOSPITALIZATION

For the past two years, CMS has based the partial hospitalization program (PHP) APC per day payment rates for hospitals and community mental health centers (CMHC) on hospital-based PHP data only. This is because including the CMHC PHP claims data would have precipitously lowered the PHP payments, generating concerns about the appropriateness of payment for PHP services and possible closure of hospital-based programs with resulting difficulties for beneficiaries in accessing partial hospitalization care. The AHA strongly supported CMS' approach for paying for hospital-based PHP services in 2009 and 2010.

CMS' 2011 analysis of more recent claims data again shows significant decreases in CMHC costs, confirming that CMHCs have a lower cost structure than hospitals. In order to continue to protect hospital-based PHPs from receiving inadequate payments, given that they offer the widest access to PHP services, both in terms of their widely dispersed geographic locations and higher intensity of services, CMS notes that it can no longer ignore the pattern. Therefore, for 2011, CMS proposes to compute four separate PHP per diem payment rates – two APC rates for CMHC PHP services, using CMHC data only and two APC rates for hospital-based PHPs services using hospital-based PHP data only.

The AHA supports CMS's decision to continue to use only hospital data to set payment rates for hospital-based PHP services in 2011. Not only have hospital-based PHP median costs been consistent and stable from the start of the OPPS, but hospital data are also more reliable, as they are based on detailed and audited cost reports that are more sophisticated than the CMHC financial reporting system. We agree that the difference in median costs that CMS has seen over recent years between CMHC and hospital-based PHP services reflect real differences in these facilities' cost structures and that these differences should be reflected in the Medicare payment rates.

However, hospitals are concerned that reducing payment for CMHCs by 42 percent in a single year, as CMS proposes to do, could result in many of these organizations going out of business, particularly those that see a high proportion of Medicare beneficiaries. As there is already inadequate inpatient and outpatient hospital capacity in many communities to care for mentally ill individuals, additional CMHC closures would have substantial and serious consequences for hospitals and for Medicare beneficiaries requiring partial hospitalization services. Such potential consequences include reduced access to an appropriate PHP for this vulnerable Medicare beneficiary population and increases in ED crowding. **The AHA urges CMS to think carefully about these possible implications and consider phasing in the payment reductions for CMHC-based PHP services over two to three years.**

AMBULATORY SURGICAL CENTER ISSUES

ASCs: Quality Data Reporting

The Tax Relief and Health Care Act of 2006 mandated that the Secretary include ASCs in the outpatient quality reporting program. CMS declined to do so in the 2008 – 2010 OPPS/ASC final rules, stating its intent to implement quality reporting for ASCs in a future year.

In the 2011 proposed rule, CMS again delays implementing quality reporting for ASCs. Instead, CMS cites the ACA requirements that it develop a plan on implementing a value-based purchasing program for ASCs that will consider measures of quality and efficiency, and states its intent to submit a report to Congress containing this plan by January 1, 2011.

The AHA supports the implementation of a value-based purchasing program for ASCs, including appropriate quality and efficiency reporting measures as a critical part of the system. All providers that perform the same services should be held to the same accountability standards with respect to the quality of the care they deliver. Likewise, patients deserve the same transparency about the quality of care from all facilities where they may seek a particular service. It is a disservice to patients that they have access to surgical quality information from hospital outpatient departments, but the same level of transparency from ASCs is nonexistent.

ASCs: Cost Reporting

Under the methodology of the new 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.

ASCs: Updating the ASC Conversion Factor and the Incorporation of Productivity
The ACA requires that the update factor for the ASC payment system, the ambulance fee schedule, the clinical laboratory fee schedule, and the durable medical equipment, prosthetics, orthotics and supplies fee schedule be reduced by an annual productivity adjustment, referred to as the multifactor productivity (MFP) adjustment, beginning January 1, 2011. This proposed rule provides the Secretary's proposed estimate of the figure to be used for CY 2011 as 1.6 percent. The rule further states, "Comments on the specific mathematical calculation of the MFP should be made to that Medicare Physician Fee Schedule proposed rule."

However, in the Medicare physician fee schedule proposed rule, CMS provides no details on the data and calculations that it used in making these estimates, instead referring readers to the Bureau of Labor Statistics, which only provides historical data. This level of information is insufficient for public comment. **Before implementing these adjustments, which will cut billions of dollars from providers, CMS should fully disclose the methods and data sources used for this estimate for public comment.**

The AHA is further concerned that current economic conditions are distorting the factor used for the productivity adjustment, potentially leading to unintended consequences. The original intent of the productivity adjustment was to hold providers to a standard of productivity improvement achieved by the rest of the economy. However, when productivity gains are driven by undesirable trends in the economy, this adjustment could lead to excessive cuts. The current "jobless recovery" is inflating productivity as output increases but a key input – employment – continues to stagnate. Cutting providers by this inflated figure could hurt hospitals and other health care providers that have been one of the few sources of continued job growth in this economy.

GRADUATE MEDICAL EDUCATION (GME)

Reductions and Increases to Hospitals' Full Time Equivalent (FTE) Resident Caps for GME Payment Purposes (Sec. 5503)
The ACA requires a redistribution of unused residency training positions as a way to encourage increased training of primary care physicians and general surgeons. Specifically, for cost-reporting periods beginning on or after July 1, 2011, hospitals will lose 65 percent of their unused or unfilled residency positions (based on the three most recent cost-reporting periods ending March 23, 2010) and qualifying hospitals will be able to request up to 75 new positions.

An appropriate supply of well-educated and trained physicians is essential to ensuring access to quality health care services for all Americans. The Association of American Medical Colleges (AAMC) projects a shortage of as many as 150,000 doctors in the next 15 years. While the redistribution of unused residency slots is a good first step, we are concerned that there will be an insufficient supply of doctors to appropriately treat the 32 million newly insured under the health reform law. In addition, a vast majority of hospitals are ineligible for the redistributed slots because they are not in one of the 17 qualifying states (including the District of Columbia and Puerto Rico), which, by law, are those with a low resident-to-population ratio or high proportion of population living in a health professional shortage area (HPSA), or in a rural area. A number of hospitals are training residents above their Medicare funded cap. **The AHA will continue to push Congress to increase the total number of Medicare-funded residency positions.**

In the rule, CMS proposes policies for determining whether, and by what amount, a hospital's FTE resident cap would be reduced. As required by law, CMS proposes to exclude rural hospitals with fewer than 250 beds. Also as required by law, CMS proposes to exclude hospitals that participated in the voluntary residency reduction program (VRRP), the New York Medicare GME Demonstration, and the Utah Medicare GME Demonstration. Specifically, CMS proposes to exclude these hospitals, whether or not they withdrew from the demonstration prior to its completion, as long as these hospitals submit a plan to CMS by December 1, 2010 specifying how they plan to fill any unused slots by March 23, 2012.

In addition, CMS proposes special treatment for low Medicare utilization hospitals, such as children's hospitals. The agency indicates that if a low-utilization hospital does not have a cap for Medicare payment purposes, or, if it has a cap but did not file Worksheet E-3 Part IV as part of its cost report in all three most recent cost reporting periods ending March 23, 2010, it would be exempt from a cap reduction. These same low-utilization hospitals, however, would be eligible to apply for an increase in their residency positions, subject to the same qualification set forth for all other hospitals. Finally, CMS proposes policies for hospitals whose caps have been reduced or increased under Section 422 of the MMA. Specifically, CMS would take into account any reductions to residency levels made under Section 422 of the MMA but not include any increases in residency counts. Under this same provision, CMS acknowledges that hospitals that received increases to their caps may still be building their residency programs and that it would be premature to remove any of these residency slots. The AHA supports all of these proposals, which will allow a number of hospitals to appropriately retain their current Medicare FTE resident caps.

CMS proposes that all other hospitals would be exempt from a resident cap reduction only if the hospital trains at, or above, its otherwise applicable resident level in <u>all</u> of its three most recent cost reporting periods ending before March 23, 2010. This proposed policy would penalize hospitals that are truly using their residency positions. For example, a hospital could be training residents under its cap in 2007, but be training at or over its cap in 2008 and 2009. According to CMS' proposal, this hospital would undergo a residency cap reduction and would lose 65 percent of its unused residency positions based on data from its 2007 cost report. We do not believe this was Congress' intent. If a hospital is training at or above their cap in *at least one year* of its three most recent cost reporting periods, then it should be exempt from a cap reduction. **The**

AHA recommends that CMS eliminate residency slots for a hospital that is training *below* its otherwise applicable resident level in all of its three most recent cost reporting periods ending before March 23, 2010.

Similar to Section 422 of the MMA, CMS proposes to use estimated information in determining possible reductions to a hospital's Medicare residency cap. In addition, the agency will provide hospitals with a time-limited opportunity to review any cap reductions for possible technical errors before the reductions are finalized. The AHA is pleased that CMS will give hospitals this critically important opportunity.

Some hospitals that have resident levels below their FTE resident caps have entered into Medicare GME affiliation agreements with other hospitals that would have otherwise exceeded their resident caps. Section 422 of the MMA had protections for hospitals that were members of the same affiliated group. The ACA, however, did not contain a similar provision. In fact, it used wording that defined "reference resident level" and "otherwise applicable resident limit" with respect to a hospital. Given this language, in the rule CMS proposes to reduce an individual hospital's resident cap even if the Medicare GME affiliated group as a whole is training residents above the group's aggregate resident cap. First, the AHA assumes that the hospital that received the slots through the agreement will be the hospital to "lose" the slots (rather than the hospital that "loaned" the slots) but further clarification by the agency is needed. Secondly, the AHA continues to believe that redistributing slots that are currently filled and used in affiliated group arrangements was not Congress' intent; we will continue to work with Congress on a technical fix to resolve this problem in the statute.

Counting Resident Time in Nonprovider Settings (Sec. 5504)
The ACA allows a hospital to count all the time that a resident trains in a nonhospital site for the purposes of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payment so long as the hospital incurs the costs of the residents' salaries and benefits during the time the resident spends in the nonhospital setting. Hospitals no longer need to incur "all or substantially all" of the costs for the training program in the nonhospital setting. In addition, the law allows hospitals to share the costs of resident training at nonhospital sites, as long as the hospitals divide the resident time proportionally according to a written agreement. The AHA is pleased by these changes in law, which will make it less administratively burdensome for hospitals to support resident training in non-hospital sites.

The law also requires hospitals to maintain records indicating the amount of time residents spend training at nonhospital sites relative to a base year, and to make the documents available to the HHS Secretary, effective for cost reporting periods beginning on or after July 1, 2010. CMS proposes to: (1) use rotation schedules to establish the amount of time residents spend training in nonhospital sites, both in the base year and in subsequent years; (2) use cost reporting periods beginning on or after July 1, 2009 and before June 30, 2010 as the base year; (3) require hospitals to maintain records of the total unweighted DGME FTE count of resident training in nonhospital settings, and (4) to include several additional cost report lines for hospitals to submit data – one for each of their primary care programs and one for all other programs.

The AHA is concerned about the potential administrative burden this last requirement will have on hospitals. While we are pleased that CMS has not requested a separate cost report line for each and every residency program at a hospital, we are concerned about the need to break out each primary care program. The intent of this provision was to make it *easier* for hospitals to train residents in nonhospital settings. We understand and support the desire to track whether an increase in this training has occurred. However, we are fearful that this overly burdensome, additional record keeping requirement on each and every primary care program is excessive. **To the extent CMS feels compelled to amend the hospital cost report to monitor ambulatory rotations, the AHA encourages CMS to consider adding just two additional lines to the cost report – one to track nonhospital resident activities in all primary care programs and one to track nonhospital programs in all nonprimary care programs.** This information should be sufficient for CMS and Congress, to determine whether the change in policy has spurred an increase in resident training in outpatient settings.

Counting Resident Time for Didactic, Scholarly and Other Activities (Sec. 5505)
The ACA allowed hospitals to count certain non-patient care activities for DGME and IME purposes – including conferences, seminars and research associated with the treatment or diagnosis of a particular patient – if those activities occur in nonprovider settings. The law also allows hospitals to count residents' vacation, sick leave and other approved leave time towards the hospital's DGME and IME resident count as long as the leave does not prolong the total time the resident participates in the program. The AHA is pleased by the changes in the law, which will make it administratively easier for hospitals to qualify for DGME and IME payments. While these are good first steps, we believe that additional improvements can be made to the program. The "splitting hairs" that CMS has encouraged and adopted over the years has become incredibly administratively burdensome for hospitals. In the interest of maintaining high-quality GME programs, the AHA believes that Medicare should pay its entire fair share of resident training costs if the resident is in an approved program. We will continue to advocate with Congress and the administration to adopt changes that would make the GME program easier for hospitals and the agency to administer.

WHOLE HOSPITAL AND RURAL PROVIDER EXCEPTIONS TO THE PHYSICIAN SELF-REFERRAL PROHIBITION

CMS proposes to revise the physician self-referral and related provider agreement regulations to implement the new limitations on use of the whole hospital and rural provider exceptions to the physician self-referral prohibition. These changes are required by Sec. 6001 of ACA, as amended, which:

- Banned the use of both the whole hospital and rural provider exceptions for *new* physician-owned hospitals; and
- Established the conditions under which self-referrals to existing physician-owned hospitals would be allowed to continue, including adherence to conflict of interest protections, *bona*

fide investment rules, patient and public ownership disclosures, reporting to HHS, patient safety rules, nondiscrimination requirements and limitations on growth.

CMS' proposed rule implements the basic provisions in Sec. 6001, but it does not address the process for requesting exceptions to the growth restriction on existing physician-owned hospitals reporting to HHS, or enforcement procedures, all of which generally do not take effect until late 2011 or early 2012.

In our view, the proposal carefully follows the relevant statutory provisions in Sec. 6001 and reflects congressional intent in clarifying the interaction of various effective dates for different aspects of the statutory changes – those that took immediate effect on the date of enactment, those that take effect at the end of this year and those that take effect in early 2012. **The AHA recommends that CMS continue to adhere closely to the statutory language of Sec. 6001 and related congressional intent.** We look forward to an opportunity to comment on the upcoming proposed rules on exceptions to the growth restrictions and the enforcement procedures