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October 7, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: **CMS-1506-P**
Comments to Proposed Rule
Hospital Outpatient Prospective Payment System and the CY-2007 Payment Rates Proposed Hospital Coding and Payments For Visits

Dear Dr. McClellan:

This firm represents Lawrence & Memorial Hospital in New London, Connecticut. We are pleased to submit the enclosed Comments to the above Proposed Rule on behalf of Lawrence & Memorial Hospital.

Sincerely yours,

Paul E. Knag

Paul E. Knag

TO: Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

FROM: Lawrence & Memorial Hospital
New London, CT

DATE: October 6, 2006

RE: **CMS-1506-P**
Comments to Proposed Rule
Hospital Outpatient Prospective Payment System and the CY-2007 Payment Rates Proposed Hospital Coding and Payments For Visits

I. *Introduction and Background Information*

Lawrence & Memorial Hospital ("Hospital") is an acute care general hospital located in New London, Connecticut. The Hospital is the major provider of health care services, including emergency health care services, in its service area. The Hospital operates a dedicated emergency room on its main hospital campus on a 24 hour per day, 7 day per week basis. The Hospital also operates a hospital based satellite emergency facility away from its main campus, the Pequot Health Center, in Groton, Connecticut. The Pequot Health Center operates seven days per week from 7:00 a.m. to 11:00 p.m. each day.

CMS has proposed in its Proposed Rule on The Hospital Outpatient Prospective Payment System and the CY-2007 Payment Rates (the "2007 OPPS Proposed Rule") to create separate payment schedules for what it has characterized as "Type A Emergency Departments" which operate on a 24 hour per day, 7 day per week basis and "Type B Emergency Departments" which operate on less than a 24 hour per day, 7 day per week basis. The so called Type B Emergency Departments would be paid at clinic rate levels which are substantially less than full emergency department rates and which do not reflect the skilled personnel, capital and other resources necessary to provide care to patients who require emergency department services. The only distinction between Type A and Type B Emergency Departments is that Type B Emergency Departments operate on a less than 24 hour per day, 7 day per week basis. In this case, the Hospital operates its Emergency Department on a 24 hours per day, 7 day per week basis, but the satellite location is closed during certain hours of the day. Nevertheless, the apparent effect of the CMS classification will be that the Hospital's satellite facility should be billed as a Type B Emergency Department at the substantially lower clinic level rates.

Hospital operates its Emergency Department on a 24 hours per day, 7 day per week basis, but the satellite location is closed during certain hours of the day. Nevertheless, the apparent effect of the CMS classification will be that the Hospital's satellite facility should be billed as a Type B Emergency Department at the substantially lower clinic level rates.

The Hospital believes since its Emergency Department does operate on a 24/7 basis, it should be able to bill at emergency department rates for both locations. Requiring that the satellite bill at the clinic rate is unwarranted both with respect to the services provided at the satellite emergency room and the legal requirements with which the satellite emergency room must comply.

The Hospital believes that CMS should permit emergency departments which are open 24 hours per day, seven days per week to bill at Type A Emergency Department rates for all locations, even though the Emergency Department includes a satellite facility not open 24 hours per day, seven days per week, pending the results of its study of resource utilization as contemplated by the proposed rule.

II. *The Lawrence & Memorial Satellite Facility*

The Pequot Health Center operates as part of the Hospital's Emergency Department. The same medical and operating policies and procedures and standards govern each Emergency Department location. Services at the satellite facility are provided by physicians who are credentialed to provide services at either location. Emergency Department personnel may work both in the 24-hour per day Emergency Department on the main campus or in the satellite facility.

The Pequot Health Center complies fully with all laws and standards relating to emergency departments, including all CMS policies which implement the Emergency Medical Treatment and Active Labor Act ("EMTALA"). Consequently, the Hospital has devoted the same full spectrum of resources to the satellite Emergency Department which are devoted to its main campus location, including personnel, technology and equipment.

The Pequot Health Center is held out to the public as a full service emergency medical care facility and receives and provides the full spectrum of emergency care to Medicare patients and all other patients in need of emergency care. The care is equivalent to any 24 hour per day Emergency Department, including Lawrence & Memorial Hospital's main campus Emergency Department.

The Pequot Health Center may receive patients who have suffered heart attacks, strokes, trauma and the full range of other conditions which result in persons needing emergency medical care. More specifically, care provided at the Pequot Health Center may include thrombolytic therapy for heart attack cases, and the diagnosing and initiation of treatment for pulmonary emboli (clots in the lungs). Abdominal aortic aneurysms, diverticulitis, fractured hips, closed head injuries can all be diagnosed and their treatment initialized at Pequot. With the latest 16 slice CT scanning ability available, ultrasound services and complete laboratory services including cardiac enzymes, BNP's, and d-dimers, Pequot is able to make any diagnosis necessary

for the patient to be a direct admission to the hospital floor – whether to a critical care bed, telemetry, or otherwise, thus bypassing an often congested emergency facility at the main campus. Pequot is a true emergency facility that helps to provide easier access to Medicare patients at a time of crisis.

Also, specialists such as orthopedists, ENT, cardiology, general surgery and the medical specialties and sub-specialties similarly come to this facility to render care and treat their patients. In short, Pequot Health Center functions in the same manner as the Hospital's main campus Emergency Department.

III. *The Pequot Health Center Has the Same Legal Obligations and Requirements as 24-Hour Per Day Emergency Facilities*

The Pequot Health Center must comply fully with all laws and standards relating to emergency departments, including all CMS requirements which implement EMTALA. In particular, it is worth noting that CMS has consistently refused to distinguish between emergency departments which operate on a 24-hour per day basis and those which do not so operate for purposes of EMTALA. As stated by CMS in 2003 in developing its final EMTALA rule:

> We are not using the Arizona bill 24-hour or 8-hour requirements because we believe an objective measure based on outpatient visits for the treatment of emergency medical conditions will be easier to understand and implement and better reflects the operating patterns of some emergency departments, including those at small or rural hospitals, or both, that may not offer treatment for emergency medical conditions continuously on a 24-hour, 7 days a week basis. (The hospital CoPs governing emergency services of hospitals (§ 482.55) and CAHs (§485.618) do not require that emergency departments be operated continuously. Under some circumstances, such as local shortages of emergency care personnel or limited demand for emergency services, hospitals and CAHs may choose to open and staff their emergency departments on less than a 24-hour 7 days a week basis.)

68 Fed Reg. 53231 (September 9, 2003, effective November 10, 2003).

The definition of "dedicated emergency department" does not require that the emergency department be open 24 hours per day, 7 days per week.

> *Dedicated emergency department* means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:
>
> (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

> (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
>
> (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

42 C.F.R. § 489.24(b). Also, "[h]ospital with emergency department" is simply defined to mean "a hospital with a dedicated emergency department as defined in this paragraph (b)." 42 C.F.R. § 489.24(b).

In the 2007 OPPS Proposed Rule, CMS has again stated that specific legal obligations are imposed on a hospital's dedicated emergency department (DED) and that these obligations apply regardless of whether the emergency department is opened 24 hours per day or less than 24 hours per day. CMS first describes the statutory obligations of a DED:

> Sections 1866(a)(1)(I), 1866(a)(N), and 1867 of the Act imposed specific obligations on Medicare-participating hospitals and critical access hospitals that offer emergency services. These obligations concern individuals who come to a hospital's dedicated emergency department (DED) and request examination or treatment for medical conditions, and apply to all of these individuals, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867(h) of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire about the individual's payment method or insurance status. Section 1867(d) of the Act provides for the imposition of civil money penalties on hospitals and physicians responsible for failing to meet the provisions listed above. . . .

CMS-1506-P, p. 329.

CMS then restates its position that EMTALA obligations are imposed on a facility which meets the definition of a DED but is not open 24 hours per day.

> We believe that every emergency department that meets the CPT definition of emergency department also qualifies as a dedicated emergency department under EMTALA. However, we are aware that there are some departments or facilities of hospitals that meet the definition of a DED under the EMTALA regulations but that do not

> meet the more restrictive CPT definition of an emergency department. For example, a hospital department or facility that meets the definition of a DED may not be available 24 hours a day, 7 days a week. Nevertheless, hospitals with such departments or facilities incur EMTALA obligations with respect to an individual who presents to the department and requests, or has requested on his or her behalf, examination or treatment for an emergency medical condition. . . .

CMS-1506-P, p. 330. Thus, CMS has made clear again this year that a DED must meet EMTALA requirements even if it does not operate on a 24-hour per day basis.

Similarly the Medicare CoPs for emergency services require that: "[t]he Hospital must meet the emergency needs of patients in accordance with acceptable standards of practice." 42 C.F.R. § 482.55. This regulation also addresses necessary staffing and requires that: "There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility." Id. §(b)(2). Thus, there is a specific legal requirement that a facility maintain sufficient trained emergency personnel to address anticipated emergency situations. However, there is no requirement that emergency services must be provided 24 hours per day, 7 days per week.

It is clear, based on the above discussion, that CMS expects emergency facilities to maintain the resources needed to fulfill their mission and that emergency facilities operating on a less than 24-hour per day basis must meet the same legal requirements as are emergency facilities operating 24 hours per day. In particular, this discussion shows that CMS considers emergency departments operating less than 24 hours per day to be dedicated emergency departments for all legal purposes. Consequently, the Pequot Health Center must provide the necessary resources, and incur the costs of such resources, to provide these services. These services, and the resources necessary to provide these services, are not required of hospital outpatient departments or clinics. Given the expectation of CMS with respect to the operation of such emergency departments, these facilities should not be compensated as if they were outpatient clinics.

IV. *CMS Has Articulated No Principled Basis for Distinguishing Type B Emergency Departments From Type A Emergency Departments for Purposes of Payment*

The sole basis for distinguishing between a Type A Emergency Department and a Type B Emergency Department, as set forth above, is that a Type B Emergency Department does not operate on a 24-hour per day basis. We understand that the 24-hour requirement has its origin in *Current Procedural Terminology (*"CPT") code definitions which have been adopted by the American Medical Association ("AMA") as a basis to classify patients who receive emergency department services for payment purposes under the outpatient prospective payment system.

CMS has acknowledged, however, on a number of occasions that CPT codes are not an adequate way to determine the cost of Emergency Department services. In the 2007 OPPS Proposed Rule, for example, CMS states:

> [T]he majority of all CPT code descriptors are applicable to both physician and facility resources associated with specific services. However, we believe that CPT E/M codes were defined to reflect the activities of physicians and do not describe well the range and the mix of services provided by hospitals during visits of clinic and emergency department patients and critical care encounters. . . .

CMS-1506-P, p. 326. CMS makes this point again later on in the 2007 OPPS Proposed Rule stating:

> However, since the beginning of the OPPS, we have acknowledged that the CPT E/M codes do not adequately describe the facility resources required to perform the services.

Id. at 586. CMS goes on to state that it is, therefore, proposing G-codes to be used by hospitals to report clinic and emergency visits, and critical care services, which describe hospital resource use. Id.[1]

Given that CMS has affirmatively stated that CPT E/M codes do not adequately describe the facility resources required to perform emergency services, CMS should not use an element of the CPT E/M code, i.e. the 24-hour per day requirement, to distinguish between Emergency department locations which operate on a 24-hour per day basis and those which operate on a less than 24-hour per day basis.

The result of the classification of an Emergency Department as a Type B Emergency Department is that payment for visits will be made at the lower clinic rates. However, CMS has candidly acknowledged that it lacks data to support this classification. After discussing the requirement that a hospital department or facility that meets the definition of a DED must still meet EMTALA obligations, even if it is not open 24 hours per day, 7 days per week, and stating that, for this reason, such facilities must bill at clinic visit codes for their services, CMS admits: "We have no way to distinguish in our hospital claims data the cost of visits provided in DEDs that do not meet the CPT definition of emergency department from the costs of clinic visits." CMS-1506-P, p. 330. Said differently, CMS is here acknowledging that it has no data to support its implicit determination that a Type B Emergency Department will be adequately reimbursed by being paid for services at clinic rates.

In fact, there are indications in the 2007 OPPS Proposed Rule that there is data that indicates that the cost of providing services is significantly higher for emergency visits than it is for clinic visits. CMS states, specifically, in the course of discussing its CY 2007 proposed payment policy: "Hospital claims data indicate that the cost of providing a visit of the same

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[1] To our knowledge, CMS has never adopted the 24-hour per day standard in a rulemaking proceeding.

level is generally significantly higher for emergency visits in comparison with clinic visits, with a differential increasing in higher levels of services." CMS-1506-P, pp. 336-37.

There is no reasoned basis for assuming, as CMS appears to have done, that Type B Emergency Departments will be adequately reimbursed based on being paid at clinic rates. We have provided in Section II examples of the emergency medical issues which the Pequot Health Center addresses on an ongoing basis. Clearly, an outpatient department of a hospital or a clinic does not have to address such issues and does not have to maintain the personnel or resources, including physical plant resources, equipment, and technology necessary to address these situations (and meet requirements under EMTALA).

Based on the above discussion, CMS should not classify emergency departments offering services on a less than 24-hour per day basis differently from other emergency departments and pay such emergency departments at clinic rates. As set forth in detail above: (1) the CPT E/M codes are an inadequate device to measure the hospital resources which need to be devoted to an emergency department visit; (2) hospital claims data indicate that the cost of providing a visit of the same level is generally significantly higher for emergency visits in comparison with clinic visits; and (3) there are numerous resources, set forth above, which must be maintained by a DED in order to treat patients who present with emergency conditions not only as a matter of providing proper care, but to meet EMTALA requirements.

V. *Existing Emergency Department Locations which Are Part of an Acute Care Emergency Department Which Operates on a 24 Hour Per Day, 7 Day Per Week Basis Should not be Compensated at Clinic Rates.*

In the 2007 OPPS Proposed Rule, CMS states that it is proposing to pay for emergency visits to Type B Emergency Departments at the same rate as clinic visits and is requiring Type B Emergency Departments to report specific G-codes for emergency visits. CMS explains that the basis for this is as follows:

> While maintaining the same payment policy for CY 2007, the reporting of specific G-codes for emergency visits provided in Type B dedicated Emergency departments will permit us to specifically collect and analyze the hospital resource costs of visits to these facilities in order to determine whether a future proposal of an alternative payment policy may be warranted.

CMS-1506-P, p. 588.

CMS then goes on to state that: "An alternative would be to provide payment for services billed by Type B Emergency Departments at payment rates other than the clinic visit rates." Id. CMS then rejects this alternative because it does "not know what the hospital facility costs of these visits would be because [CMS is] unable to identify these services in [its] historical claims data." CMS then goes on to state:

> In some respects, their costs may resemble the costs of visits to clinics because they may not be available 24 hours per day or may not require the same high state of readiness of Type A Emergency Departments. In other respects, their costs may resemble the costs of visits to Type A Emergency Departments because they both provide predominantly unscheduled visits. Therefore, we currently would have no accurate methodology for establishing payment rates that are appropriate for visits to Type B Emergency Departments. Therefore, consistent with past payment policies for certain services, such as drug administration, in which we maintained current payment policies while gathering more detailed cost data, we are proposing to continue payment to Type B Emergency Departments at clinic rates while we gather hospital claims data specific to these visits to review their costs.

Id. at pp. 588-89.

CMS acknowledges, therefore, that the costs of an emergency department location which operates on a less than 24-hour per day basis may resemble the costs of 24-hour per day emergency department location. Yet, CMS determines still to reimburse such emergency department locations at clinic rates rather than at other rates.

The Hospital believes that CMS should not resolve its uncertainty as to costs against paying Type B Emergency Departments at rates less than Type A Emergency Departments. It will be much better policy for CMS to pay at full emergency department rates while the issue is being studied. Such a payment policy would be more likely to provide adequate reimbursement and be consistent with the position or CMS that a DED meet all applicable legal requirements, such as EMTALA, even if it operates less than 24-hours per day.

VI. *Summary*

The Pequot Health Center is an integral part of the Emergency Department of the Lawrence & Memorial Hospital Emergency Department. The Emergency Department of Lawrence & Memorial Hospital operates on a 24 hour per day, 7 day per week basis. As the Pequot Health Center is an integral part of the Hospital's Emergency Department which operates 24-hours per day, services rendered there should be reimbursed at full emergency department rates.

Moreover, the Pequot Health Center is held out to the public as a full-service Emergency Department. It is required by law to meet the same legal requirements including, but not limited to, EMTALA requirements as is any Emergency Department open on a 24 hour per day, 7 day per week basis. It treats serious emergency cases as set forth above and is required to maintain the personnel and other resources necessary to do so.

Consequently, there is no proper basis for classifying a facility such as the Pequot Health Center as a Type B Emergency Department and reimbursing such a facility at clinic rates. Clearly, an outpatient clinic is not required to receive emergency cases and to maintain the personnel, physical facilities, equipment, supplies, and technology as is a facility such as the Pequot Health Center. There is no basis in fact for assuming that the Pequot Health Center will be adequately reimbursed, as required by the Medicare program, by being paid clinic rates. Indeed, as discussed above, CMS itself acknowledges that it lacks data on this issue.

CMS should reimburse the Pequot Health Center and existing like facilities at emergency department rates while CMS gathers data and further studies this issue. The Hospital shares the concern of CMS with access. Paying facilities such at the Pequot Health Center at emergency department rates would in no way adversely affect access to emergency medical services. Indeed such reimbursement can only promote access to needed emergency services for Medicare and other patients by allowing for the continued operation of such facilities.

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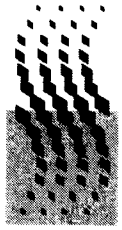

Vascular
SOLUTIONS

October 10, 2006

VIA: FED EX

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Hospital Outpatient Prospective Payment System and CY 2007 ASC Payment Rates, CMS-1506-P

To Whom This May Concern:

These comments are submitted on behalf of Vascular Solutions, Inc., a leading manufacturer of state-of-the-art medical products and systems that employ novel surgical laser technologies to treat diseases of the vascular system. Our products include the Vari-Lase® Endovenous Laser System, which offers a highly effective and less invasive treatment for symptomatic venous insufficiency.

We appreciate the opportunity to comment on the CY 2007 OPPS proposed rule with comment period published by the Centers for Medicare & Medicaid Services (CMS) on August 23, 2006, which provides, among other changes, an update of the OPPS payment system and the CY 2007 ASC covered procedures list. See Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, 71 Fed. Reg. 49506 (August 23, 2006).

We specifically comment on two items: 1) the assignment of CPT 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein) and add-on code CPT 36479 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites) to ASC payment group 9, and 2) the reassignment of CPT 36478 and 36479 from APC 0091 to APC 0092. We believe that

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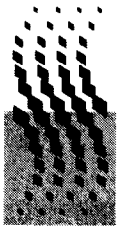

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CMS made a clerical error in addendum AA and listed these codes as assigned to ASC payment group 8 but meant to list payment group 9. As for the APC change, we believe that this change is unwarranted and that these codes properly belong with comparable codes 36475 and 36476 (radiofrequency vein ablation) in APC 0091.

CMS discusses its decision to assign CPT 36478 and 36479 to ASC payment group 9 on page 49630 of the proposed rule. But in first column of addendum AA on page 49737 of the proposed rule, it lists the ASC payment group for these codes as payment group 8. We presume this inconsistency to be a mere clerical error and that the correct assignment is group 9 as discussed in the preamble of the proposed rule.

Regarding the APC assignment for these codes, CMS originally assigned CPT 36478 and 36479 to APC 0091 based on clinical and resource similarity of these codes with procedures currently assigned to APC 0091. As long as two-times rule is not violated, there is no reason to change the APC for 36478 and 36479.

Clinically, laser vein ablation (described by 36478 and 36479) accomplishes the same objective as the radiofrequency vein ablation, i.e., the treatment of diseased and incompetent veins. Resource consumption in each of these procedures is also similar, with only a relatively small difference between the costs of laser versus radiofrequency.

We are concerned that the proposed different APC assignments (0092 for laser and 0091 for radiofrequency) will result in both underpayment for the laser procedure and an artificial competitive advantage for the radiofrequency procedure. Therefore, we recommend that CMS maintain CPT 36478 and CPT 36479 in APC 0091 and not change these codes to APC 0092.

Vascular Solutions appreciates the opportunity to comment on the OPPS proposed rule and we are eager to provide CMS with any additional information that would enable the agency to properly evaluate this matter. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me at (763) 656-4349.

Sincerely,

Deborah L. Neymark

Deborah L. Neymark
Vice President, Regulatory Affairs, Clinical Research and Quality Systems

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October 9, 2006

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HEALTH CORPORATION

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P - Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

I am the Vice President of Development and Professional Services of Titan Health Corporation in Sacramento, California. Titan Health Corporation manages eleven surgery centers across eight states. Each year, our surgery centers provide outpatient surgical care to Medicare beneficiaries. Ensuring appropriate payment for Medicare services is vital to our ability to serve our community. Please accept the following comments regarding Section XVII of the proposed rule, which would make revisions to policies affecting ambulatory surgical centers for CY 2007. 71 Fed. Reg. 49505 (August 23, 2006).

I. Proposed ASC List Update Effective for Services Furnished On or After January 1, 2007

A. Criteria for Additions to or Deletions from the ASC List

We commend CMS for proposing to update the ASC list for CY 2007, but believe the update falls short by not making extensive revisions to the criteria used to determine which procedures may be reimbursed in the ASC setting. As a result, beneficiary access to ASC services will continue to be limited by arbitrary criteria in CY 2007.

1. The inclusionary ASC list should be abandoned.

The limited, inclusionary list of covered ASC procedures is no longer the best way to address the safety and appropriateness of ASC services. Within currently accepted standards of medical practice - in which vast numbers of procedures may performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient procedural services.

First, and most importantly, the ASC list limits the ability of physicians to select the site of service they believe is most clinically appropriate for their patients. A physician's assessment

of the medical needs of the patient and the capabilities of the facility should determine whether a patient receives care in the ASC setting.

Second, the list limits Medicare beneficiaries' access to procedures that many other patients routinely receive in ASCs. Private payers do not restrict the access of their insured to ASC services. Decisions regarding the site of service are recognized to be the province of the insured's physician. As a result, several minimally invasive procedures not available to Medicare patients in the ASC setting, such as spinal disc decompression and laparoscopic cholecystectomy, are commonly performed for selected privately insured patients - at significant savings to the patient and to the insurer. As long as CMS continues to maintain an ASC list, Medicare beneficiaries' access to appropriate services will always lag behind that of the private sector.

The ASC list should be abandoned. In its place, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and develop a list of services specifically excluded from coverage. In fact, CMS already has such an exclusionary list; for purposes of hospital outpatient payment under the Outpatient Prospective Payment System, CMS has developed and uses an "inpatient only" list. Because Medicare-certified ASCs have proven over the past two decades that they are capable of safely performing the same scope of services provided in hospital outpatient departments, this list may also be used to identify procedures excluded from coverage in ASCs.

Alternatively, if CMS develops a separate exclusionary list for ASCs, then that list should be based on the criteria identified by MedPAC in their March 2004 report. Specifically, MedPAC recommended the current list of ASC approved procedures by replaced "with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay".

2. The criteria used to revise the Medicare list of procedures that may be performed in an ASC are outdated and do not serve the interest of the Medicare program or its beneficiaries.

Section 1833(i)(1) of the Social Security Act requires CMS to determine which surgical services are safely and appropriately offered in an ASC. CMS selects the services represented on the current list of approved procedures based on criteria outlined in the Code of Federal Regulations at §416.65. We believe CMS is inappropriately limiting beneficiary site-of-service choices by continuing to make procedure list determinations using obsolete and outdated criteria that CMS itself previously proposed to substantially revise (63 Fed. Reg. at 32298).

a. Requirement that procedures be commonly performed in an inpatient setting.

When the Medicare ASC benefit was originally implemented in the 1980s, most surgical procedures were performed in an inpatient setting. In the intervening decades, the outpatient setting has become the accepted setting for many types of surgical procedures. As new clinical approaches to surgery, anesthesia and pain management have been incorporated into standard medical practice, certain procedures have moved almost exclusively to the outpatient environment. New procedures have evolved that were never commonly performed in an

inpatient setting. Examples include newer arthroscopic and endoscopic interventions, and surgical treatments using laser or radiofrequency instrumentation. These procedures were developed predominately in an outpatient setting and are performed safely and cost-effectively on thousands of commercial insurance and self-pay patients each year.

To continue to require that a procedure be commonly performed in the inpatient setting before it can be deemed appropriate for the ambulatory surgery setting is no longer consistent with current standards of practice. We recommend general standard (1) "Covered surgical procedures are those surgical and other medical procedures that are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC" be eliminated as obsolete. This recommendation is also supported by MedPAC's 2004 report which specifically states, "it no longer makes sense to consider inpatient volume when updating the ASC list."

b. Requirement that a procedure not be commonly performed in physicians' offices

Current CMS guidelines provide that a procedure performed 50 percent or more of the time in a physician's office cannot be reimbursed in an ASC. In effect, this limits a physician's options to an inpatient or HOPD setting for patients for whom an office setting would be inappropriate. The higher costs generally associated with inpatient and HOPD reimbursement as compared to ASC reimbursement rates have been well documented by the OIG and MedPAC. Eliminating ASCs as an option for procedures which can be safely performed in the outpatient setting imposes unnecessary costs on both the Medicare program and individual beneficiaries. Conversely, allowing ASCs to serve as a site-of-service option to HOPDs for care has allowed the Medicare program to achieve significant cost savings.

While physicians may safely perform many procedures on healthy Medicare beneficiaries in the office setting, sicker beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. A brief summary of these factors follows.

Patient Characteristics – Patient characteristics affect the selection of the appropriate site of service. Factors such as body habitus, comorbid conditions and even the patient's ability to lie in certain positions or hold still for long periods of time may affect whether a procedure can or should be performed in a physician office.

Another consideration is whether other procedures are being performed at the same time. If a patient is having a procedure performed in an ASC and another procedure that can be performed in an office is also needed, the patient and the Medicare program benefit from having both procedures performed at the same time.

Additionally, a procedure may be scheduled for a facility when the physician thinks it likely that a diagnostic procedure will result in the need for a therapeutic intervention. For example, a diagnostic cystoscopy (CPT code 52000) may be scheduled at an ASC because the

physician thinks it likely that a cystoscopy with biopsy (CPT code 52204), requiring instruments and cautery not available in the office, will be necessary.

Procedure Differences –Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12-20 biopsies. Due to the more invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

Office Differences – Physician offices vary greatly in terms of equipment and personnel. To a great extent, this varies based upon the volume in the office. A small office may simply not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

State Laws and Regulations – State laws and regulations impose limitations on what can be done in offices. To be able to perform certain types of procedures, these state provisions may require specific equipment, staff or even accreditation. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

As was noted in the preamble to the interim final rule of May 2005, the rate of performance in ASCs of the physician office procedures originally proposed for deletion has remained relatively stable over the past 10 years. In other words, the inclusion of these procedures on the ASC list has not induced substantial shifts in sites of service, which suggests site-of-service selection is being driven by clinical need. If CMS remains concerned about the potential for financial incentives to improperly influence site-of-service selection, then the logical solution is to address any unjustified payment variations in the new payment system, rather than denying ASC coverage for procedures commonly performed in physician offices.

MedPAC has also recommended that CMS abandon the requirement that procedures be performed less than 50 percent of the time in physician offices to be added to the list. The Commission has specifically stated, "Physicians should have the discretion to decide which setting is most clinically appropriate for individual patients."

c. Operating and recovery time limits are unnecessary.

The ASC industry supported CMS's 1998 proposal (63 Fed. Reg. at 32298) to discontinue using the time limits on operating, anesthesia, and recovery time currently defined under 42 C.F.R. § 416.65(b), which are used as a basis for determining whether a procedure should be added to or deleted from the ASC List. The numeric threshold rules presently employed by CMS are obsolete and too often result in the exclusion of procedures that are entirely appropriate for the ASC setting. The current rule that the ASC List should be restricted to procedures that generally do not require more than 90 minutes operating time or 4 hours recovery time is outdated. This standard was developed in the early 1980s and predates numerous technological advances that are now standard in the ASC setting. Both thresholds are arbitrary and without clinical significance.

As MedPAC has observed, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting. With the development of short-acting general anesthetics, the length of operating time is immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Moreover, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours.

B. Procedures Proposed for Addition to the ASC List

We commend CMS for updating the ASC list again for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clearly clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. We believe the HOPD data is a more reliable proxy for the cost of providing this service.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in the physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service; significant error rates (80 % and higher) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe continued reliance on this data is appropriate.

As noted above, there is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to overutilization of those procedures in the ASC setting. CMS itself has acknowledged that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696).

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must been seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also costs both the program and its beneficiaries significantly more. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment, the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility

setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a humane examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this

magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CMS should also add G0289, which describes a knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

There are several procedures that are appropriate additions to the ASC list. We believe that CMS should add these procedures to the list with an effective date of January 1, 2007.

CPT Code	**Descriptor**
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

II. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

We are supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). We also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:".

We are also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is our belief that the items CMS finds necessary for review should be published in the Federal Register, as any change in regulation should be open to review and comment by the public before being implemented.

* * * * *

Thank you for considering our comments. If you have any questions or need additional information, please do not hesitate to call me at 916-614-3600.

Sincerely,

Catherine Nichol

110

GlaxoSmithKline

October 6, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Dear Dr. McClellan:

On behalf of GlaxoSmithKline (GSK), I welcome the opportunity to submit comments on the proposed rule relating to the Medicare hospital outpatient prospective payment system (OPPS) published in the *Federal Register* on August 23, 2006 (Volume 71, No. 163, p. 49506). GSK is a world-leading research-based pharmaceutical company dedicated to improving the quality of human life by enabling people to do more, feel better and live longer. The company is an industry leader, with significant products in several therapeutic areas - anti-infectives, HIV, central nervous system (CNS), respiratory, gastro-intestinal, metabolic, cardiovascular and oncology. In addition, it is a leader in the important area of vaccines.

My comments will focus on BEXXAR® (Tositumomab and Iodine I 131 Tositumomab), a cancer therapy approved by the Food and Drug Administration on June 30, 2003 for the treatment of certain patients with non-Hodgkin's lymphoma (NHL). The BEXXAR® therapeutic regimen differs from traditional chemotherapy in that the entire treatment takes place over 7-14 days as a single, one time therapeutic intervention as opposed to multiple repeated cycles. The approval of BEXXAR® was the culmination of a decade of research and development and marked a significant advance for patients with NHL who had been waiting for new treatment options. The September 2006 issue of the *Journal of Clinical Oncology* reports the latest clinical results showing an overall response rate of 91%, including a 69% complete remission rate. After a median follow-up time of 5.1 years, the estimated 5-year overall survival rate was 87%, and the progression-free survival rate was 67%.

GSK has worked closely with CMS to address coding and payment issues to ensure that Medicare patients' continue to have access to BEXXAR®. The payment policies implemented for CY 2006 are particularly significant for the constructive approach they embrace to make an appropriate payment in the current year while collecting data for future years' rate-setting. In contrast, we are extremely concerned about the changes proposed for CY 2007. CMS proposes to base the 2007 payment rates solely on 2005 claims data, which are problematic due to the phenomenon of cost compression which is a particular issue for Radiopharmaceuticals with higher acquisition costs. If the proposed policies are adopted in the final rule, Medicare's payment rates will fall significantly below the costs hospitals incur in providing BEXXAR® therapy. As shown in the table below, hospitals would lose about $10,500 for each administration of BEXXAR® considering only the drug acquisition costs.

In addition to these costs, hospitals also incur a radio-pharmacy compounding fee of approximately $3,000 to acquire both the dosimetric (dx) and therapeutic (tx) radioactive components and deliver them in a form ready to be administered to patients (See sample range of compounding fees in ATTACHMENT B). It is important to note that GSK does not provide any discounts, rebates or other price reductions except for a 2% prompt pay discount that is offered to direct purchasers who hold receivables and this has been our policy since the introduction of BEXXAR®. Finally, for reference, at launch on June 30, 2003, the total WAC of the four drug components in the BEXXAR® regimen was $26,000 compared to the current WAC of $26,780.

		WAC	CY 2005 Payment Rate	CY 2006 Payment Rate	CY 2007 (proposed) Payment Rate
G3001*	Supply and administration of tositumomab, 450 mg	$2,188.75	$2,250.00	$2,250.00	$1,510.52
G3001*	Supply and administration of tositumomab, 450 mg	$2,188.75	$2,250.00	$2,250.00	$1,510.52
A9544***	I131 tositumomab, dx	$2,317.50	$2,241.00	Cost-Based**	$1,368.17
A9545***	I131 tositumomab, tx	$20,085.00	$19,422.00	Cost-Based**	$11,868.78
	TOTAL	$26,780	$26,163.00	$4,500.00 + Cost-Based**	$16,257.99

* G3001 is billed twice (administered prior to the dosimetric dose and administered prior to the therapeutic dose).
** Payment varies by hospital. Hospital charges for radiopharmaceuticals with Status Indicator H are based on all costs associated with the acquisition, preparation, and handling in order for payments to accurately reflect all actual costs.
*** A9544 was formerly C1080; A9545 was formerly C1081

To assure continued patient access to therapy, GSK recommends that the 2006 policies be continued in 2007 coincident with policies to collect data on which to base the payment rates in 2008. These recommendations are described in detail below.

THE BEXXAR® THERAPEUTIC REGIMEN

The administration of BEXXAR® involves four separate steps on two distinct days, which together comprise the BEXXAR® therapeutic regimen:

On the first day the patient receives

1. The administration of unlabeled tositumomab monoclonal antibody, 450 mg followed by

2. The administration of a dosimetric dose of I-131 tositumomab. Subsequent to administration of this dose, three scans are performed and calculations are made to determine the patient-specific therapeutic dose (Item #4 below).

Once the patient specific therapeutic dose has been determined, the patient then receives

3. The administration of a second dose of unlabeled tositumomab monoclonal antibody, 450mg followed by

4. The administration of a patient-specific therapeutic dose of I-131 tositumomab.

Adequate Medicare payment for these products is critical for patient access to this important therapy. GSK has worked closely with CMS to explain the issues surrounding BEXXAR® to ensure that Medicare reimbursement did not impact patient access. Unfortunately, particularly in 2005, when Medicare payment rates were based on 83% of AWP, hospitals were uncomfortable applying an appropriate mark-up over costs in establishing charges for BEXXAR®. Thus, the CMS proposal to set 2007 rates based on 2005 claims data will result in inappropriate and inadequate payment rates for BEXXAR®.

CY 2006 OPPS PROPOSED RULE

In the proposed rule for 2006, CMS proposed a temporary 1-year policy to pay for radiopharmaceutical agents that are separately payable based on hospital's charges for each radiopharmaceutical agent adjusted to cost using hospital-specific cost-to-charge ratios (CCRs). Further in this same proposed rule, CMS stated that "Should ASP data be unavailable for Radiopharmaceuticals for CY 2007, it is not apparent to us what methodology we could use to establish payment rates for these items in CY 2007 other than the hospital CY 2006 claims-based methodology".

GSK strongly supported CMS' proposal for radiopharmaceutical reimbursement. Implementation of the interim payment policy using hospital specific charges adjusted to costs would allow treating institutions to appropriately charge for all costs associated with acquisition, preparation and handling of BEXXAR® .and that this methodology would allow additional time to develop appropriate coding and payment policies in the longer term. GSK also provided specific recommendations that CMS could provide to facilitate the reporting of accurate charges and an appropriate claim, by providing 1) clarification of which cost-to-charge ratio would apply to each hospital, 2) a template that hospitals may use to prepare their claims for radiopharmaceuticals, including handling and other costs, and 3) an appendix that reflects the instructions that will be given to fiscal intermediaries regarding the implementation of this structure.
Finally, GSK suggested that G3001, applicable to both unlabeled tositumomab and its administration, be amended to be applied only to the product. In addition, we recommended that hospitals be allowed to use 90784 (APC 359) for the administration of unlabeled tositumomab and strongly urged CMS to retain G3001 as a product-only code, useable only in the context of the BEXXAR® therapeutic regimen.

CY 2006 OPPS FINAL RULE

In the final rule, CMS adopted a temporary one-year policy to pay for separately payable radiopharmaceuticals at charges reduced to cost, where payment was determined using each hospital's specific overall CCR. Hospitals were instructed to set charges for radiopharmaceuticals based on all costs associated with the acquisition, preparation, and handling in order for payments to accurately reflect all actual costs associated with making these products available to patients. CMS indicated that it anticipated different purchasing, preparation and handling practices to be reflected in these charges. Based on our experience with hospitals, this was viewed as a fair policy that would allow them to cover their costs and there was neither a financial incentive nor disincentive to use the product.

2007 OPPS PROPOSED RULE

In the absence of ASP data for radiopharmaceuticals, CMS considered three alternatives for setting 2007 rates. One option was to continue the 2006 policy of basing payment on billed charges reduced to costs. Of the available options to set 2007 rates, this approach has the greatest potential to provide an adequate payment in the current year while collecting data to use to set rates in future years. CMS did not propose this option, however, and instead proposes to set rates based on 2005 billed charges. In addition, CMS proposes to reassign G3001 to a clinically appropriate APC and use CY 2005 claims data to determine the median costs on which payments would be based. The proposed payment rate for G3001 in 2007 would decrease from $2,250.00 to $1,510.52.

Based on hospitals' acquisition cost for BEXXAR®, as detailed in the table at the front of these comments, the proposed 2007 payment rates for BEXXAR® would fall significantly short of meeting the statutory requirement to pay the average acquisition cost of the product. In fact, the proposed 2007 payment rate would cover only approximately 60% of the wholesale acquisition cost for the product. We are concerned about the proposed elimination of the current 2006 policy.

BEXXAR® is a radiopharmaceutical and meets the definition of a sole source drug. Therefore, under the requirements of the MMA, it qualified as one of the 'specified covered outpatient drugs.' As such, the CY 2005 payment rate was based on 83% of AWP. Under this payment methodology, there was no reason for hospitals to set charges appropriately. As a result, the 2005 charges do not serve as a relevant proxy for setting prospective payment rates based on the mean cost calculated using hospital claims.

We also note that MedPAC's conclusions about handling costs are not accurate in the case of BEXXAR®. MedPAC believes that hospitals' billed charges for drug products generally include handling costs. Enclosed with these comments, we are submitting hospital invoices that show separate charges for BEXXAR® and for the radio-pharmacy preparation costs (Attachment B). Thus, charges for handling are not included in most hospitals' CY 2005 charges for BEXXAR®. As noted, charges set by hospitals were based on the CY 2005 payment rate of 83% of AWP and did not include the additional cost of compounding incurred by hospitals. As directed by the CY 2005 OPPS Final Rule, the estimated $3,000 cost to hospitals for radio-pharmacy compounding was to be reported "as a separate line item charge with an appropriate revenue code or packaged into the charge for CPT codes 78804 and 79403, which could result in an outlier payment if the outlier threshold for those services was exceeded." Given this scenario, the compounding fee typically was not included in the billed charges for BEXXAR®.

RECOMMENDATIONS

Given our concern that the proposed Medicare payment rates would be a significant barrier to Medicare eligible patient access to radio-immunotherapy for the treatment of Non-Hodgkin's Lymphoma, we respectfully submit the following recommendations for CY 2007 payment policies applicable to BEXXAR® therapy:

Recommendation 1: Consistent with the recommendation of the APC panel, GSK recommends that CMS extend the current CY 2006 cost-based policy for radiopharmaceutical agents for one additional year, i.e., through CY 2007. While we recognize that the CY 2006 payment policy was intended to be temporary, we strongly believe that it must be continued for one additional year to both preserve access to these crucial therapies and to enable CMS to establish appropriate payment rates and methodologies for CY 2008.

Recommendation 2: Distinguish between radio-immunotherapy agents (used as therapeutics for the treatment of cancer) and radio-pharmaceuticals (often used as diagnostic imaging agents) and require manufacturers of radio-immunotherapy agents to submit average sales price (ASP) data. Beginning in CY 2008, payment rates for separately payable radio-immunotherapy agents would be set using the ASP methodology.

If ASP methodology is adopted for radio-immunotherapies, CMS would need to establish a distinct code for compounding of these agents that would reflect the reasonable and necessary separate costs associated with the safe and effective preparation and handling of these agents ready for patient administration. Based on our available invoices, we would estimate that the payment rate be set at approximately and $3,000. We note that these policies would enable CMS to set fixed national payment rates for the acquisition and handling of separately payable radioimmunotherapies.

Under the proposed rule for CY 2007, the payment rate for G3001 would decrease to $1,510.52, which is approximately 30% below the acquisition price for the product. From 2004 to 2006, the payment rate for G3001 was $2,250.00. The current WAC for tositumomab is $2,188.75 and, as noted, GSK does not currently provide any discounts, rebates or other price reductions except for a 2% prompt pay incentive discount that is offered to direct purchasers.

Additionally for CY 2007, CMS should maintain the payment rate for G3001 (Supply and administration of tositumomab, 450 mg) at the current level of $2,250. Because of the previously discussed issues with the CY 2005 claims data for BEXXAR® therapy, it is not appropriate to set the CY 2007 rate for this code using median costs derived from CY 2005 claims data. Furthermore, GSK repeats its previous request that G3001, applicable to both unlabeled tositumomab and its administration, be amended to be applied only to the product. We recommend that CMS provide hospitals with the appropriate administration code for a 1 hour infusion (e.g., 90780 – IV Infusion therapy, one hour) to permit hospitals to bill for the administration of unlabeled tositumomab.

We note that unlabeled tositumomab alone is only FDA approved as part of the overall BEXXAR therapeutic regimen and therefore cannot be used other than as part of BEXXAR® therapy. As such, it should be assigned a specific code and appropriately paid.

Finally, we note that the NDC numbers changed in July 2006 reflecting the GSK acquisition of BEXXAR® from Corixa (Attachment A).

We thank you for the opportunity to submit these comments and we appreciate your thoughtful consideration of each of the recommendations described above. Please contact me if you have questions or would like to request supporting data from GSK.

Sincerely,

Roger A. Hunter
Executive Director
New Product Planning and Policy
GlaxoSmithKline Oncology and Acute Care

ATTACHMENT A
Discontinued and New NDC Numbers for BEXXAR® Components and Current Wholesale Acquisition Cost

New NDC No.	Product Description	Package Size	Wholesale Acquisition Cost*
0007-3260-31 ***Effective date 7/14/06***	Tositumomab Kit for Dosimetric Step	2 x 16.1 mL 1 x 2.5 mL	$ 2,188.75
0007-3260-36 ***Effective date 7/14/06***	Tositumomab Kit for Therapeutic Step	2 x 16.1 mL 1 x 2.5 mL	$ 2,188.75
0007-3261-01 ***Effective date 7/19/06***	Iodine I 131Tositumomab, Dosimetric	20.0 mL	$ 2,317.50
0007-3262-01 ***Effective date 7/19/06***	Iodine I 131Tositumomab, Therapeutic	20.0 mL	$20,085.00

Discontinued NDC No.	Product Description	Package Size
67800-101-31	Tositumomab Kit for Dosimetric Step	2 x 16.1 mL 1 x 2.5 mL
67800-101-32	Tositumomab Kit for Therapeutic Step	2 x 16.1 mL 1 x 2.5 mL
67800-111-10	Iodine I 131Tositumomab, Dosimetric	20.0 mL
67800-121-10	Iodine I 131Tositumomab, Therapeutic	20.0 mL

*Wholesale Acquisition Cost is the listed price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates, or chargebacks. Listed price may not represent prices charged to other customers, including specialty distributors.

ATTACHMENT B
Sample Invoices

American Hospital Association

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(202) 638-1100 Phone
www.aha.org

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Rm 445-G
Washington, DC 20201

Ref: [CMS-1506-P and CMS-4125-P] Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program – HCAHPS Survey, SCIP, and Mortality (71 Federal Register 49506), August 23, 2006.

Dear Dr. McClellan:

On behalf of our 4,800 member hospitals, health care systems, and other health care organizations, and our 35,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (PPS) for calendar year (CY) 2007. The rule also includes proposals on inpatient quality reporting for fiscal year (FY) 2008, ambulatory surgical center (ASC) payments for 2007 and 2008 and Medicare Administrative Contractors.

Our analysis of the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2007 than in 2006. These changes make it extremely difficult for hospitals to plan and budget from year to year. We would expect that four years after the start of the outpatient PPS, the payment rates and associated payment-to-cost ratios would be much more stable.

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

The proposed rule contains several significant policy changes in the outpatient PPS and in other areas of Medicare policy. We will address the 2008 policy and payment changes for ASCs in a separate comment letter that will be sent prior to CMS' November 6 deadline. Also, the AHA and the American Health Information Management Association will send jointly a letter on CMS' specific proposals on emergency department (ED) and clinic visits. We address all other areas briefly in this cover letter and in more detail in the attachment.

LINKING INPATIENT QUALITY DATA REPORTING TO OUTPATIENT PPS UPDATE

The AHA and its member hospitals are committed to public transparency of hospital quality information. Indeed, as a member of the Hospital Quality Alliance (HQA), the AHA has worked toward increasing the amount of publicly available, reliable and useful quality data. We continue to work through HQA to identify and implement important clinical quality measurement activities for the nation's hospitals. This work includes collaborating with the AQA (formerly known as the Ambulatory Quality Alliance) to identify measures that are specifically appropriate for and applicable to the hospital outpatient setting.

For CY 2007, CMS has proposed to use its authority under §1833(t)(2)(E) of the *Social Security Act* to reduce the outpatient PPS update for those hospitals that are required to report quality data under the hospital inpatient PPS, but failed to do so. Specifically, CMS proposes that hospitals that failed to submit the required quality data for a full market basket update for inpatient PPS for FY 2007 would have their outpatient update also reduced by 2 percentage points.

We are troubled by CMS' proposal for many reasons: First, it simply makes no sense to link outpatient payments to inpatient measures of quality. Second, linking a reduction in the conversion factor to the submission of inpatient PPS data that have already been reported and made public does nothing to further CMS' stated goals of encouraging hospital accountability and quality improvement. Third, linking payment to data submission that predates the outpatient PPS rule is unfair and tantamount to retroactive rulemaking. Fourth, in linking outpatient payments to the reporting of quality data, CMS has exceeded its statutory authority.

We urge CMS to rescind its proposal to link inpatient quality reporting to the outpatient payment update and rely on the efforts of the HQA and AQA to develop outpatient quality measures.

FY 2008 INPATIENT QUALITY MEASURES

In the proposed rule, CMS announces the measures that hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to receive the full inpatient payment in FY 2008. The AHA applauds CMS for adding to its requirements for a full inpatient payment in FY 2008 measures that have been adopted by the HQA. These well-designed measures represent aspects of care that are important to patients and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. We urge CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA.

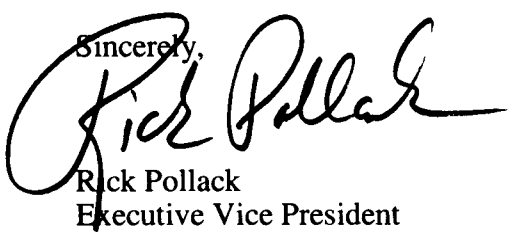
We also commend CMS for proposing in August the measures that hospitals will be required to report to receive their full FY 2008 inpatient payments. This early notice allows hospitals sufficient time to establish the proper data collection processes. We urge CMS to continue with this timely rulemaking as a mechanism to notify hospitals several months in advance of the inpatient PPS quality reporting requirements for the upcoming fiscal year.

HOSPITAL CLINIC AND ED VISIT CODING

The AHA is disappointed that in 2007 CMS proposes to establish new G codes to describe hospital clinic visits, ED visits and critical care services in the absence of national guidelines. Creating temporary G codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G codes for Medicare and current procedural terminology (CPT) codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. In contrast, the AHA recommends that the CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized. This would provide for stability for hospitals in terms of coding and payment policy and allow CMS and stakeholders to focus on developing comprehensive national hospital visit guidelines that could be applied to a new set of hospital visit codes in the future.

The AHA appreciates the opportunity to comment. The attached detailed comments expand on the points raised above and also on several other important proposals in the rule. If you have questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273.

Sincerely,



Rick Pollack
Executive Vice President

The American Hospital Association's Detailed Comments on the Proposed Rule for the 2007 Outpatient Prospective Payment System

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OUTPATIENT PPS ISSUES

QUALITY REPORTING AND UPDATING OUTPATIENT PPS PAYMENTS

The AHA and its member hospitals support the goal of public transparency of hospital quality information. Indeed, as a member of the Hospital Quality Alliance (HQA), the AHA has worked toward increasing the amount of publicly available, reliable and useful quality data. We continue to work through HQA to identify and implement important clinical quality measurement activities for the nation's hospitals. This work includes identifying measures that are specifically appropriate for and applicable to the hospital inpatient setting.

For calendar year (CY) 2007, the Centers for Medicare & Medicaid Services (CMS) has proposed to use its authority under § 1833(t)(2)(E) of the *Social Security Act* to reduce the outpatient prospective payment system (PPS) update for those hospitals that fail to report quality data as required under the inpatient PPS. Specifically, CMS proposes to reduce the outpatient update by 2 percentage points for hospitals that fail to submit the quality data required for a full market basket update for the fiscal year (FY) 2007 inpatient PPS.

We are troubled by CMS' proposal for many reasons. First, it simply makes no sense to link outpatient payments to inpatient measures of quality. Second, linking a reduction in the conversion factor to the submission of inpatient PPS data that have already been reported and made public does nothing to further CMS' stated goals of encouraging hospital accountability and quality improvement. Third, linking payment to data submission that predates the outpatient PPS rule is unfair and tantamount to retroactive rulemaking. Fourth, in linking outpatient payments to the reporting of quality data, CMS has exceeded its statutory authority.

1. CMS should not use inpatient quality measures in the outpatient setting.
In the proposed rule, CMS asserts that the clinical quality measures for inpatient PPS are proxies for hospital outpatient performance measures and that outpatient-specific measures are needed for the outpatient setting. The inpatient PPS measures are not, in fact, appropriate proxies for outpatient PPS measures, for reasons articulated below.

The measures of heart attack, heart failure, pneumonia and surgical infection prevention are not appropriate proxies of outpatient care quality. These measures are based on solid scientific evidence about what constitutes effective treatment for patients with heart attack, who are undergoing major surgeries, or who are in heart failure or suffering from community-acquired pneumonia to the point that they require hospitalization. They reflect significant steps in the care of hospitalized patients that have been linked to clear medical evidence of improved patient outcomes if these steps are followed as the patients are admitted, during their hospitalization, and as they are discharged. In other words, the measures are specified in a manner that they apply only to patients who are admitted to

the hospital. For example, we know that patients diagnosed with an acute myocardial infarction and who have no contraindications for receiving particular medications, have a better outcome if given aspirin and beta blockers within a short time of when they first present. We do not know whether patients who come to the emergency department with chest pain, are diagnosed with some condition other than a heart attack, and then go home, have a better outcome when they are given aspirin.

Furthermore, there is little or no relationship between the measures being used to assess the adequacy of care provided to an inpatient with a heart attack, heart failure, pneumonia and surgical care and an assessment of care to patients in the outpatient setting. In addition, certain of the inpatient measures apply only during a hospitalization (e.g., whether the chosen antibiotic was discontinued after 24 hours if there is no indication of infection from surgery, or whether the patient was given medication to address his/her left ventricular systolic dysfunction) or when an inpatient is discharged (e.g., prescriptions for continuation of beta blockers). Effective quality measurement assesses whether the individual received the right care at the right time. While there may be some steps in caring for outpatients that are similar to those for patients requiring inpatient admission for heart failure and pneumonia, the guidelines overall will be different for the outpatient. **Linking the reporting of inpatient quality measures to outpatient payment creates a disconnect between the care setting and payment system.**

In the final inpatient PPS rule for FY 2007, CMS said "that stakeholder input is an essential part of the measure selection process." The HQA and AQA (formerly known as the Ambulatory Quality Alliance) were established specifically to bring relevant stakeholders together to agree on effective measures of the quality of care for inpatient and ambulatory care settings and to find ways to make performance data available to the public.

We urge CMS to continue working with the HQA and AQA to identify and implement measures that truly assess aspects of outpatient care quality, and when appropriate measures have been identified, work with Congress to consider how the payment system should be altered to support the provision of high-quality care in the outpatient setting. **Because appropriate outpatient care measures have not been identified, CMS should eliminate any link between inpatient quality measures and outpatient hospital payments.**

2. The proposal does not further CMS' stated goals.

In the proposed outpatient rule, CMS said that "the collection and submission of performance data and the public reporting of comparative information about hospital performance can provide a strong incentive to encourage hospital accountability in general and quality improvement in particular." The AHA agrees with this view. We disagree, however, with what must have been CMS' conclusion – albeit unstated – that linking outpatient payments to the submission of previously reported inpatient PPS quality data furthers CMS' stated goals.

Under CMS' proposal, outpatient payments would be reduced if a hospital failed to submit the data required for the inpatient PPS market basket update. Those data are based exclusively on inpatient quality measures. We see no way to encourage accountability or quality improvement in the outpatient setting by linking payment to inpatient performance measures. In addition, because obtaining the full market basket update under the inpatient PPS depends upon the submission of inpatient quality data, hospitals already have a very strong incentive to provide the inpatient PPS quality data to CMS. In fact, according to CMS' own data, 99 percent of affected hospitals share their data. Moreover, eligibility for the inpatient PPS market basket update has already been or will be determined before CMS publishes the outpatient PPS final rule. A hospital can do nothing now or once the final rule has been published to alter its eligibility for the inpatient PPS market basket update. Therefore, linking outpatient payments to the submission of inpatient PPS quality data provides no additional incentive for hospitals to submit those data.

3. Linking outpatient payments to the prior submission of inpatient data is tantamount to retroactive rulemaking.

As explained above, CMS has proposed to link payments under the outpatient PPS to eligibility for the full market basket update under the inpatient PPS; however, eligibility for the inpatient PPS market basket update has already been or will have been determined before CMS publishes its outpatient PPS final rule. Thus, hospitals can take no action now or, if CMS adopts this proposal in a final rule, in the future, to avoid a reduction in their CY 2007 outpatient PPS conversion factor. This is patently unfair and tantamount to retroactive rulemaking.

In the proposed outpatient PPS rule, CMS said the "determinations concerning which hospitals fail to meet the requirements for receiving the full update to the outpatient PPS conversion factor in CY 2007 will be available on or about September 1, 2006." That is long before the final outpatient PPS rule will be published. Thus, eligibility for CY 2007 outpatient PPS payments would be contingent on actions that occurred even before CMS established its CY outpatient PPS payment rules. Linking future reimbursement to actions that occurred in the past and which cannot be altered now is unjust and conflicts with the way in which CMS approached the submission of quality data under the inpatient PPS.

In responding to comments regarding the submission of quality data for the FY 2007 inpatient PPS update, CMS explained that its goal was to improve "quality through public reporting in an efficient manner that does not create an undue burden." (71 Fed. Reg. 48,032.) In the text that immediately followed, CMS went on to delay, by two calendar quarters from the quarter specified in the proposed rule, the date for requiring hospitals to submit quality data for an expanded set of inpatient PPS quality measures. CMS said that the delay "would afford hospitals adequate notice . . . " Id. at 48,033.

Because the inpatient PPS eligibility determination will have been made before the outpatient PPS rule is final, linking outpatient PPS payments to the inpatient PPS does

nothing to improve data reporting; rather, it is simply a potential financial burden for hospitals. Similarly, if CMS wants to "afford hospitals adequate notice" in setting the date for requiring the submission of quality data under the outpatient PPS, then the agency should not now establish a rule that ties to a period in which hospitals lacked notice of CMS' plans. Doing so would be inequitable, at best.

4. CMS exceeded its statutory authority to "ensure equitable payments" in linking outpatient payments to eligibility for the inpatient PPS update.

In the preamble, CMS explained its proposal to link payment under the outpatient PPS to eligibility for the inpatient PPS market basket update. Specifically, CMS said:

> We are proposing to employ our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adapt the quality improvement mechanism provided by the inpatient PPS . . . program for use in the outpatient PPS. As we have discussed above, failure to account at all for quality in payment systems raises a fundamental issue of payment equity. In the absence of mechanisms that provide incentives for higher quality care, Medicare's payment systems can direct more resources to hospitals that do not deliver high quality care to Medicare beneficiaries. (71 Fed. Reg. 49,667.)

In the AHA's view, basing outpatient PPS payment on eligibility for the inpatient PPS update is anything but equitable. CMS goes to some lengths to argue in favor of accounting for quality in payment systems, but never explains how its outpatient PPS proposal would actually do that. In our view, the outpatient PPS discussion regarding "equitable adjustments" is a pretext for permitting CMS to do what Congress has never given the agency authority to do.

Congress expressly established the link between quality data reporting and the payment update in inpatient PPS and in the home health payment system. If Congress wanted outpatient PPS updates to be linked to reporting inpatient quality data, it would have made that change expressly. Because Congress did not explicitly authorize CMS to take such action, the agency has attempted to find authority for this unprecedented link elsewhere.

The AHA believes that CMS has stretched too far in concluding that the "equitable payments" provision is that authority. CMS simply makes an unexplained and, we believe, inexplicable, leap in logic in concluding first, that the desirability of accounting for quality results in payment inequities in outpatient PPS, and second, that reducing the conversion factor is the means to address those inequities. This type of adjustment is not what Congress intended in enacting the "equitable payments" provision.

In the only case to have considered the breadth of the "equitable payments" provision, the U.S. Court of Appeals for the District of Columbia Circuit made clear that there is a legally significant distinction between an "adjustment" on the one hand and substantial departure from or a restructuring of, a statutory scheme on the other hand. Amgen v.

Smith, 357 F.3d 103 (D.C. Cir. 2004). The "equitable payments" provision permits the former and prohibits the latter.

Reducing the conversion factor as CMS proposes is a substantial departure from the statutory scheme and can hardly be called an "adjustment." As the D.C. Circuit said:

> Limitations on [CMS's] equitable adjustment authority inhere in the text of § [1833](t)(2)(E), which only authorizes "adjustments," not total elimination or severe restructuring of the statutory scheme." As in *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994), where the Supreme Court held that the Federal Communications Commission's authority to "modify" certain requirements could not reasonably be read to encompass the power to make "basic and fundamental changes in the scheme" such as eliminating them entirely, similar limits inhere in the term "adjustments" to those the Supreme Court found in the word "modify." Id, at 117

In this case, linking a reduction to the outpatient PPS conversion factor to submission of inpatient PPS quality data would be a "severe restructuring of the statutory scheme." The conversion factor is a crucial part of outpatient PPS and altering it can hardly be termed an "adjustment." CMS' authority under the "equitable payments" provision simply cannot "reasonably be read to encompass the power to make [such a] 'basic and fundamental change[] in the scheme.'" Id.

In summary, because Congress did not explicitly authorize CMS to link outpatient payment to inpatient data, CMS may not do so on its own. **Reliance on the "equitable payments" provision is misplaced and, as a result, CMS should not adopt the proposal to link outpatient PPS payments to eligibility for the inpatient PPS update.**

CLINIC AND ED VISITS

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

In the past several years, different models for national coding guidelines for reporting facility visit services have been proposed and reviewed by CMS. In 2002, CMS stated that it would not create new codes to replace existing CPT E/M codes for reporting hospital visits until national guidelines were developed, in response to the public's concern about implementing code definitions without national guidelines.

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

We appreciate CMS' consideration of the recommendations of the independent expert panel, and the posting of this recommendation for wider public input. While we have eagerly awaited national guidelines for hospital visits, we continue to support CMS' commitment to provide a minimum of six-to-12 months notice prior to implementing national guidelines. Sufficient time is required for providers to make the necessary system changes and educate their staff.

In response to this proposed rule, the AHA /AHIMA expert panel was reconvened. The AHA and the AHIMA jointly will submit a separate comment letter on ED and clinic visits that will describe in greater detail our recommendations.

Proposed Codes and Coding Policy for 2007. Despite CMS' previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 the agency proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are adopted, CMS states that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The AHA opposes implementing new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. CMS should drop its proposal to create temporary level II G codes while requiring hospitals to apply their own internal guidelines to these codes. Instead, we recommend that CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.

Creating temporary G codes without a fully developed set of national guidelines will increase confusion and require hospitals to manage two sets of codes – G codes for Medicare and CPT codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. In contrast, our approach would provide stability for hospitals in terms of coding and payment policy and allow CMS and stakeholders to focus on developing and fine-tuning a set of national hospital visit guidelines that could be applied to a new set of hospital visit codes in the future.

The AHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA's CPT Editorial Panel to create CPT level

I codes for hospital visits. Then hospitals could report these codes to all payers. We do not support the creation of temporary G codes as an interim step for a year or two, but prefer to wait for the implementation of CPT codes.

Proposed Payment Policy for 2007. CMS proposes to assign the new G codes to Ambulatory Payment Classifications (APCs) for payment purposes as follows:

- Five new clinic visit G codes would be assigned to five new clinic visit APCs.
- Five new type A ED visit G codes assigned to five new type A emergency visit APCs. (Type A = open 24 hours a day, seven days a week – 24/7)
- Five new type B ED visit G codes assigned to the five new clinic visit APCs. (Type B = not open 24/7)
- One new critical care G code (hosp critical care, 30-74 min) assigned to the new critical care APC. The other critical care G code (hosp critical care, additional 30 min) would be packaged into other services or procedures performed during the visit.

CMS asserts that paying for type B ED visits at the clinic visit rate is consistent with the agency's current policy for services furnished in EDs that have an *Emergency Medical Treatment and Labor Act* (EMTALA) obligation but do not meet the CPT definition of ED to be reported using clinic codes. The agency states, "Under the outpatient PPS, we have restricted the billing of emergency department CPT codes to services furnished at facilities that meet this CPT definition. Facilities open less than 24 hours should not use the emergency department codes."

In the proposed rule, CMS requests comments regarding this policy because the agency is concerned with ensuring that necessary ED services are available to rural Medicare beneficiaries, recognizing that rural EDs sometimes operate on a less than 24/7 basis. Although the AHA does not collect data on the hours of operation for hospital EDs, we believe, based on our recent discussions with state hospital associations and hospitals, that there are very few EDs that are open less than 24/7. We did learn anecdotally of several hospitals that have satellite EDs that are not open 24/7. However, we are unaware of any rural hospital EDs that operate at anything less than 24/7. In fact, many rural hospitals are designated as critical access hospitals (CAHs) for which the Medicare conditions of participation require emergency services be available 24/7. Therefore, the AHA believes that there are very few facilities that would currently meet the type B ED definition, and it is likely that most of these are remotely located EDs operated by hospitals with 24/7 on-site EDs. That said, the level of services in EDs varies based on the availability of other hospitals, general population size and availability of physician specialists.

In addition, in the proposed rule, CMS notes that the reporting of specific G codes for emergency visits provided in type B EDs will permit the agency to collect and analyze the hospital resource costs of visits to these facilities in order to determine whether a proposal of an alternative payment policy may be warranted in the future. The AHA believes that CMS' proposed policy to establish different sets of ED visit codes for type A and type B facilities will not provide adequate data to allow a useful analysis of comparative costs to charges associated with the operation of these facilities. Hospitals that have both an on-site 24/7 ED as well as one or more remote non-24/7 EDs would report costs for both types of EDs under a single service category – emergency services. Rolling costs into the same cost report line would make it impossible to distinguish between the services provided in the type A versus type B ED.

We recommend that CMS create a unique revenue code for reporting non-24/7 ED services and modify the cost report to create another service category to allow separate reporting of those costs. With this structure, the billed services provided in the on-site 24/7 ED could be captured using a different revenue code from the billed services provided in the satellite non-24/7 ED. This would allow the matching of costs to charges. This approach also would make it unnecessary to establish a separate set of codes for type B EDs. Over time, reviewing cost report data combined with patient level-of-care data will help determine whether the costs of non-24/7 EDs are more similar to those of a clinic, a 24/7 ED, or somewhere in-between.

We are concerned about CMS' proposed coding and payment structure. From a coding perspective, what should be taken into consideration are the services provided to individual patients. In addition to highlighting the traditional 24/7 availability of hospital EDs, we believe that the CPT description of ED services as requiring 24-hour services also may serve as a proxy for the level and scope of care that the facility can provide. If an ED that is open less than 24/7 can provide the same level and scope of care that an ED open 24/7 can, then it should be paid at the ED rate. For instance, this may be the case if the non-24/7 ED:

- Operates as a provider-based facility at a different location than its main campus hospital, but essentially is an extension of the main campus 24/7 ED;
- Complies with EMTALA by virtue of meeting the criteria as a "dedicated emergency department;"
- Provides unscheduled care and maintains procedures to register and triage patients;
- Accepts patients from emergency medical services (EMS), including patients who are at risk of loss of life and/or limb and require emergency stabilization; and,
- Is staffed during hours of operation similar to the hospital's on-site 24/7 ED, and provides patients with access to the same type and range of services – including

physician specialists, laboratory tests, imaging procedures and other services and procedures that are typical of emergency services provided by the on-site 24/7 ED.

From a payment policy perspective, assuming that the costs of these non-24/7 EDs are more similar to that of a clinic than a 24/7 ED is unfounded. After all, these are EDs that CMS has already defined as being subject to EMTALA by virtue of meeting the criteria as a "dedicated emergency department," including providing unscheduled emergency care and accepting ambulance patients. While these facilities may not bear the same staffing costs and "stand-by" expenses associated with 24-hour operation, they do bear these other costs and provide an intensity of service that make them closer to a 24/7 ED than an outpatient clinic.

Therefore, given the expected small number of non-24/7 EDs, and the fact that this is an interim policy pending evaluation of cost data, CMS should pay for ED visit services at these facilities at either the ED APC rate or, if appropriate, at a reasonable discount from the ED rate.

Proposed Treatment of Guidelines for 2007. The AHA is pleased that CMS finds the AHA/AHIMA guidelines to be the most appropriate guidelines to use as the starting point for consideration in the outpatient PPS. We further agree that the 2003 AHA/AHIMA guidelines require short-term refinement prior to full adoption and continued refinement over time. We are encouraged that CMS is providing the expert panel with the opportunity to refine the model and address CMS' and the field's concerns.

In the proposed rule, CMS requests comments on several areas of concern regarding the AHA/AHIMA guidelines. As stated previously, we will address these specific areas in a separate comment letter with AHIMA. We also request that CMS release the detailed analysis by the Iowa Foundation for Medical Care of the AHA/AHIMA model so we can appropriately review the issues raised.

APC Relative Weights

Proposed Recalibration of APC Relative Weights for 2007. Current law requires CMS to review and revise the relative payment weights for APCs at least annually. The AHA continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates, as this information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the August 2000 implementation of the outpatient PPS, payment rates for specific APCs have fluctuated dramatically. For 2007, the proposed rates continue to show significant volatility.

In the proposed rule, CMS uses the most recent claims data for outpatient services to set the 2007 weights and rates. The AHA continues to support the use of the most recent claims and cost report data to set the 2007 payment weights and rates. We also continue

to support the use of multi-procedure claims, as we believe these data improve hospital cost estimates. The AHA also supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures.

Proposed Revision to the Overall Cost-to-Charge Ratio (CCR) Calculation. The proposed rule includes a significant change in the way the overall hospital-specific CCR is calculated. CMS uses the overall hospital CCR to set outlier thresholds and to estimate outlier and pass-through payments and in other services paid based on charges reduced to costs. The fiscal intermediaries (FIs) use overall CCRs to determine outlier payments and payments for certain other services. CMS recently discovered that it calculates the overall hospital CCR differently than the FIs. Compared with the CMS "traditional" overall CCR calculation, the FIs' method includes allied health education costs and adds weighting by Medicare Part B charges. In the rule, CMS proposes to use features of both methods by excluding allied health education costs and adopting weighting by Medicare Part B charges.

It is important to have a consistent methodology for setting policy, modeling impacts and making outpatient PPS payments. In addition, the decisions to exclude allied health education costs and to adopt weighting by Medicare Part B charges are appropriate policy decisions. **Therefore, the AHA supports CMS' proposal to adopt a single overall CCR calculation that incorporates weighting by Medicare Part B charges and excludes allied health costs for modeling and payment.**

Proposed Changes to Packaged Services. The AHA commends CMS and the APC Packaging Subcommittee for continuing to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. In the rare circumstances in which a hospital provides services described by these "N" status codes alone, there is no way for the hospital to be reimbursed for the cost of providing these services.

The AHA supports the proposed designation of specific CPT codes as "special packaged codes" with status indicator "Q" that will be used for separate payment of these services when they are billed on a date of service without any other separately payable outpatient PPS service. We encourage CMS to continue to work with the APC Packaging Subcommittee to further review "N" status codes and identify those services that should be paid separately.

PARTIAL HOSPITALIZATION

The AHA is concerned that an additional proposed 15 percent reduction in the per-diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services and could endanger Medicare beneficiary access to them. This will be the second consecutive year that the per-diem rate was reduced by 15

percent. Hospitals cannot sustain further reductions in the per-diem rates. These services are quite vulnerable, with many programs in recent years closing or limiting the number of patients they accept.

We share CMS' concern about the volatility of the community mental health center (CMHC) data and support the agency's intent to monitor and work with CMHCs to improve their reporting.

The AHA recognizes that CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per-diem cost; however, hospitals offering partial hospitalization services should not be penalized for the instability in data reporting of CMHC-based services.

The AHA recommends that in the final rule for 2007, CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

OPPS: Rural Hospital Hold Harmless Transitional Payments

The AHA is concerned about the impact that the phase-out of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. The AHA supports S. 3606, *Save Our Safety (SOS) Net Act of 2006*, which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, CMS proposes to raise the fixed-dollar threshold to $1,875 – $625 more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment amount and at least $1,875 more than the APC payment amount.

We are concerned that CMS has set the threshold for outliers too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the AHA is concerned that Medicare may not spend the targeted outlier pool.

NEW TECHNOLOGY APCS

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. CMS generally retains a service within a new technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, CMS proposes to assign some services that have been paid under the new technology APCs for less than two years to clinically appropriate APCs. For example, positron emission tomography (PET)/computed tomography (CT) scans, which had been assigned to new technology APC 1514 in 2005, is scheduled to move to a clinical APC in 2007. Some hospitals that adopt these new technologies may be unable to quickly change their charge masters, including changing codes and setting charges that reflect actual costs of the new service. Additionally, the data that CMS obtains in the first year or two of adoption of these technologies may not appropriately reflect the use and cost of these services because diffusion of new technologies can be slow, and waiting additional years for more hospitals to adopt and use new technology is important. **Therefore, the AHA recommends that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.**

RADIOLOGY PROCEDURES

In the proposed rule, CMS indicates that it will continue to defer the implementation of a multiple imaging procedure payment reduction policy pending further analyses. **The AHA supports CMS' decision not to implement this policy.** As we commented last year, the AHA opposes this policy without better justification and more substantial hospital-based data analyses. Hospital cost data currently reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures.

In the proposed rule CMS requests comments on ways that hospitals can uniformly and consistently report charges and costs related to all cost centers that also acknowledge the tradeoff between a greater precision in developing CCRs and the administrative burden associated with reduced flexibility in hospital accounting practices.

The AHA appreciates CMS' evenhanded presentation of this issue in the proposed rule. As CMS notes, any step taken to ensure greater uniformity in the reporting of costs and charges would have to carefully balance the additional administrative burden and loss of flexibility in a hospital's accounting system.

The difficulty in applying CCR ratios to arrive at cost is that it presupposes that there is consistency in how HCPCS procedure codes relate to the service categories indicated on the cost report. The cost report relies on service categories that reflect the general descriptor of a provider's service departments. But other departments can now safely and effectively perform services that were once performed by a specialized departmental unit.

For instance, bedside lab tests are now performed in the ED; procedures can be furnished in an operating room, treatment room, or outpatient surgery area; and supplies cross multiple departments. Consequently, inconsistencies occur when determining the cost of a service if the CCR assignment is made to a different cost report service category.

CMS also must recognize the current limitations and inconsistencies in preparing the cost report. Today, providers must reconcile the Medicare Provider Statistical & Reimbursement reports to determine how FIs not only paid the claim but also how they recorded the units and revenue code assignment to the billed services. Often the FI makes changes that affect how the services and revenue matches are made. Such changes by the FI, however, fail to match the revenue as reported by the provider on the cost report.

The AHA urges CMS to proceed with care in this area. Hospitals need the flexibility to set charges and allocate costs in a manner that makes the most sense for the particular mix of services it offers. In addition, even relatively small changes in practices and procedures need to take into account the varying levels of sophistication of provider accounting systems. CMS must allow adequate time for dissemination of changes, and provider education on any changes is imperative.

DEVICE-DEPENDENT APC

Devices Replaced without Cost or with Credit to the Hospital. CMS proposes to reduce the APC payment and beneficiary copayment for selected APCs when an implanted device is replaced without cost to the hospital or with full credit for the removed device. This is in response to device recalls and field actions involving the failure of implantable devices for which manufacturers offer to replace devices without cost to the hospital or to offer credit for the device being replaced if the patient requires a more expensive one. CMS proposes to calculate the reduction to the APC payment rate using the same method it uses to calculate the pass-through rate for implanted pass-through devices. The adjustment would be implemented through the use of an appropriate modifier specific to a device that has been replaced.

Neither the Medicare program nor Medicare beneficiaries should be required to pay hospitals for devices that were provided to the hospital at no cost. In addition, while there are additional burdens on hospitals associated with imposing this new policy, hospitals have been required since January 1 to use the FB modifier with the HCPCS code for a device that was furnished to the hospital without cost. Therefore, this is not an entirely new type of policy for hospitals. **The AHA requests that CMS clarify whether and how this FB modifier would be used once the new policy goes into effect.**

Further, as CMS acknowledges in the proposed rule, the FB modifier may not be used appropriately if the replacement device is an upgrade from the device that is being removed from the patient. In any given recall, 10-20 percent of replaced devices could

result in upgrades – the physician opts to use a higher functioning device over the one being replaced in order to meet the patient's current clinical needs. In these cases, the hospital would be responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed. This price difference may be significant. For instance, in the case of implantable cardiac defibrillators, the hospital payment for the difference between the upgraded and replaced device could range between $1,000 and $7,000.

The AHA recommends that CMS revise its proposal to account for the additional cost that the hospital would bear in the event of a device upgrade. This could be accomplished through the use of a second modifier or another approach to identify when the replacement procedure involves an upgraded device. The APC offset for an upgraded device replacement should be set at a lower percentage than the APC offset made for an "even" device replacement.

OPPS: NONPASS-THROUGH DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Packaging Threshold. Due to the expiration of the *Medicare Modernization Act's* (MMA) $50 drug packaging threshold, CMS evaluated four options related to drug packaging in the proposed rule: (1) pay all drugs separately; (2) set a high-dollar threshold; (3) continue the $50 threshold; or (4) update the current packaging threshold for inflation. CMS settled upon the fourth option, opting to establish a $55 packaging threshold for outpatient drugs.

Historically, the AHA has supported more extensive packaging of drugs into the services with which they are provided because integrating these costs is a fundamental principle of a PPS, as opposed to a fee schedule. More packaging eliminates financial incentives to use the more costly drugs because they are paid separately. We also in the past have expressed concern about the coding burden related to keeping track of and educating coding staff on which drugs fall inside or outside of the packaging threshold.

However, this year we re-evaluated our rationale for supporting drug packaging and have determined that, for a variety of reasons listed below, eliminating the drug packaging threshold may pose less of a coding and financial burden than was previously the case.

- CMS has encouraged hospitals to report charges for all drugs, biologicals and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. Thus, for hospitals following this advice, revising payment policy to pay separately for all drugs with HCPCS codes would not pose an additional coding burden.

- Eliminating the packaging threshold for drugs also would eliminate the incentive for physicians and hospital staff to base drug choice on whether it is separately

paid or not and focus exclusively on a drug's clinical value for the individual patient.

- Eliminating the threshold would provide equity across settings. It would make payment in the hospital outpatient department more consistent with payment in the physician office. In the past, CMS has expressed concern that inconsistencies in payment across care settings could inappropriately drive patient site of care. But this is precisely what could happen if CMS were to maintain a drug packaging threshold in hospital outpatient departments while at the same time paying for all drugs separately, and at a higher rate, in the physician office.

- The current drug administration codes do not allow additional payment for a second or subsequent intravenous (IV) push of the same drug. Under this policy, if a second or subsequent IV push involves a packaged drug, then not only is the drug administration not reimbursed, neither is the drug itself. If these drugs were separately paid, then the hospital could charge for the drug itself and be reimbursed.

Therefore, the AHA recommends that CMS eliminate the drug packaging threshold for all drugs, biologicals and radiopharmaceuticals with HCPCS codes.

Proposed Payment for Specified Covered Outpatient Drugs. The AHA is concerned about CMS' proposal to reduce payments for specified covered outpatient drugs (SCODs) to the average sales price (ASP) plus 5 percent in 2007. This represents a 1 percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed at a rate less than the ASP plus 6 percent rate paid in a physician office. **Consistency in payment for drugs and biologicals across settings is important, which is why the AHA recommends that CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

In addition, as we commented last year, the AHA agrees with the Medicare Payment Advisory Commission that handling costs for drugs and biologicals delivered in the hospital outpatient department is significant and should be reimbursed by Medicare. We remain concerned that payments for SCODs at the proposed rate for 2007, or even at the 2006 rate of ASP plus 6 percent, does not adequately reimburse hospitals for drugs that have very high overhead and handling costs due to special equipment or procedures related to a drug's toxicity, special compounding or preparation requirements. **The AHA recommends that CMS work with stakeholders to better understand the costs involved in the preparation of pharmaceutical agents, particularly those drugs that have very high handling costs.** CMS should develop a new payment methodology that acknowledges and provides appropriate payment for those costs.

Payment Policy for Radiopharmaceuticals. CMS proposes to no longer pay for radiopharmaceutical agents at the hospital charge reduced to cost and instead to pay for

them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. We believe the claims data still are incomplete and may be incorrect as a result of frequent code and descriptor changes for radiopharmaceuticals. **Therefore, the AHA recommends that for 2007, CMS continue to use the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

DRUG ADMINISTRATION

In 2005, CMS transitioned from using daily per visit drug administration Q codes to CPT codes. In the 2006 final rule, CMS implemented 20 of the 33 new 2006 CPT codes for drug administration. The 13 CPT codes that were not implemented included concepts such as initial, subsequent and concurrent administration, which were operationally problematic for hospitals to report. CMS instead created six HCPCS C codes that generally paralleled the 2005 CPT codes for the same services.

While hospitals were grateful for CMS' responsiveness to their concerns regarding the operational difficulties of implementing the full range of 2005 CPT codes for drug administration services, they nevertheless had to implement these CPT codes for non-Medicare payers. As such, hospitals have had to overcome those operational challenges while implementing two sets of codes for reporting certain drug administration services, depending on the payer.

The AHA recommends that in 2007, CMS implement the full set of CPT drug administration codes and eliminate the six HCPCS C codes created to parallel the 13 drug administration codes that were not implemented in 2006. This policy change eliminates the burden of having to apply and maintain two sets of codes for essentially the same services.

In addition, in 2005 and 2006, CMS provided special instructions to hospitals for the use of modifier 59 in order to ensure proper outpatient PPS payments, consistent with their claims processing logic. Since CMS did not expect any changes to coding structure for 2007 and because the agency has updated service-specific claims data from 2005, CMS no longer needs specific drug administration instructions regarding modifier 59. **The AHA supports CMS' proposal that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other outpatient PPS services.**

CMS also proposes six new APCs in 2007 that are intended to better distinguish costs related to infusions of different types and furnished over different lengths of time. Previously, payment for additional hours of infusion has been packaged due to the inability to use claims data to distinguish costs associated with infusions of different duration. However, in 2005, codes used in the outpatient department distinguished

between the first hour of infusion and additional hours of infusion. Using newly available 2005 claims data, CMS proposes to assign CPT/HCPCS codes to six new drug administration level APCs, with payment rates based on the median costs from this 2005 claims data. **The AHA supports CMS' proposal to create six new drug administration APC levels which will provide more accurate payment for complex and lengthy drug administration services.**

In addition, as part of the implementation of new drug administration codes in 2006, CMS decided to no longer allow for the reporting of separate IV pushes of the same drug. This coding instruction created a situation in which no payment is made for packaged drugs that are given as separate IV pushes. The prime example is pain management where a patient may require multiple IV pushes of morphine, but only one drug administration code could be reported. Because morphine is a packaged drug, not only would the administration services involved in the subsequent IV pushes of morphine not be reimbursed, the drug itself would not be paid. We do not believe CMS' intent was to discontinue payment for this drug when it is medically necessary. **The AHA recommends that CMS make payment for a second or subsequent IV push of the same drug** by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in 2007 so that an appropriate payment is made for this service.

Further, the AHA also recommends that CMS allow providers to use all available HCPCS codes for reporting drugs to reduce the administrative burden associated with reporting drugs using only HCPCS codes with the lowest increments in their descriptors.

OPPS: OBSERVATION SERVICES

For 2007, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The AHA continues to support CMS' concept of allowing the Outpatient Claims Editor logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, now that the process for determining whether observation is separately payable is largely "automated," CMS should explore a narrow expansion in the diagnoses for which observation may be separately paid. **Therefore, the AHA recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.** This is consistent with a recent recommendation from the Advisory Panel on APC Groups.

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove eight codes from the inpatient-only list, which identifies services that are ineligible for payment if they are performed in an outpatient setting, and assign them to clinically appropriate APCs.

The AHA remains concerned about the inconsistency between Medicare payment policy for physicians and hospitals with regard to procedures on the inpatient-only list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient-only list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient-only list changes annually, physicians may not always be aware that a procedure they have scheduled in an outpatient department is on the inpatient-only list. There also may be other reasonable, but rare, clinical circumstances that may result in these procedures occurring in the absence of an inpatient admission.

The AHA continues to recommend that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient-only list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without an inpatient admission.

OTHER POLICY ISSUES

FY 2008 IPPS REPORTING OF HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE (RHQDAPU)

In the proposed rule, CMS announces the measures that hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to receive the full inpatient payment in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would have their FY 2008 inpatient payments reduced by 2 percent.

The AHA applauds CMS for adding to its requirements for obtaining full inpatient payment in FY 2008 measures that have been adopted by the HQA. These well-designed measures represent aspects of care that are important to patients and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We urge CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA.** This alignment will reinforce the importance of public

transparency on quality and help focus quality improvement efforts on the chosen high-priority areas of care.

We also commend CMS for proposing in August the measures that hospitals will be required to report to receive their full FY 2008 inpatient payments. This early notice allows hospitals sufficient time to establish the proper data collection processes. We urge CMS to continue with this timely rulemaking – using the proposed rule for outpatient PPS or a freestanding quality reporting rule – as a mechanism to notify hospitals several months in advance of the inpatient PPS quality reporting requirements for the upcoming fiscal year.

CAHs: Emergency Medical Screening

The AHA supports CMS' proposal to change the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel to screen individuals who present to a CAH emergency department, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted by the CAH's bylaws.

This change provides hospitals with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services in CAHs. We note, however, there is an inconsistency between CMS' preamble language and the regulatory text proposed in this section. While the preamble indicates that the CAH would have to include this change in their bylaws, the regulatory text does not mention CAH bylaws.

Medicare Contracting Reform Mandate

In the rule, CMS proposes regulation changes required to implement the Medicare contracting reform provisions of the MMA. Hospitals will be integral customers of the Medicare Administrative Contractors (MACs), and a significant proportion of hospital revenue will depend on these contractors operating in a timely and judicious manner.

The MMA requires that the Secretary consult with providers on the MAC performance requirements and standards, and the AHA appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the AHA believes that such provider input is critical.

However, we encourage CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so

low that they may be unable to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is used often to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

In addition, given that each defined Medicare A/B MAC jurisdiction will include several states, CMS must ensure that the chosen contractor is able to maintain a local presence. This includes the ability to work within different time zones, availability within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

CMS proposes to assign providers to the MAC that is contracted to administer the types of services billed by the provider within the geographic locale in which the provider is physically located. However, CMS also proposes to allow large national hospital chains that meet the agency's criteria as "qualified chain providers" to request an opportunity to consolidate their Medicare billing activities to the MAC with jurisdiction over the geographic locale in which the chain's home office is located. In addition, qualified chain providers that were formerly granted single FI status (prior to October 1, 2005) would not need to re-request such privileges at this time.

The AHA is pleased that the proposed rule will allow chain-provider organizations to receive "single MAC" status. However, we also believe that there should be a mechanism for a chain provider with facilities in many A/B MAC jurisdictions to consolidate into a smaller number of MACs instead of a single MAC in the chain's home office location. This might apply to a chain provider that has its home office and several of its facilities within the same MAC jurisdiction but other facilities located in another MAC's jurisdiction. For a chain organization that includes multiple kinds of providers – hospitals, freestanding imaging centers, physician offices, etc. – there should be a mechanism to allow some facilities to stay with the MAC in their geographic locale while others migrate to the MAC of the chain's home office.

The AHA also seeks clarification on how chain providers that currently report to a single intermediary will be managed in the coming stages of the MAC transition. If a chain hospital is in a jurisdiction that is transitioning to a MAC, but the chain's home office is not in that jurisdiction, may the chain hospital continue to report to the intermediary it has been using, or must it transition to the contracted MAC in its jurisdiction? The AHA recommends that CMS expeditiously provide instructions on how a chain organization may convert to a single MAC to avoid the need for multiple transitions for chain hospitals.

HEALTH INFORMATION TECHNOLOGY

In the proposed rule, CMS repeats questions posed in the proposed inpatient PPS rule regarding:

- Its statutory authority to encourage adoption and use of information technology (IT);
- The appropriate role of IT in any value-based purchasing program; and
- The desirability of including use of certified health IT in hospital conditions of participation.

Health IT is a critical tool for improving the safety and quality of health care, and the AHA's members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a shared investment between the providers and purchasers of care.

As summarized in the final inpatient PPS rule, most commenters, including the AHA, noted that health IT is a costly tool, requiring both upfront and ongoing spending. While providers bear the burden of those costs, the financial benefits of having IT systems often flow to the payers and purchasers of care, including Medicare. **Given that they reap many of the financial benefits of IT, the AHA believes that the payers and purchasers of care should share in its costs.** An add-on payment to Medicare is one possible mechanism for doing so.

With regard to value-based purchasing, the AHA believes that these programs should build on the consensus measures endorsed by the broad spectrum of organizations, including CMS, that participate in the HQA. In general, the HQA favors measures that address quality process and outcomes, rather than the tools used to get there. Health IT, however, can play a role in reducing the burden of quality reporting.

In the FY 2007 final inpatient PPS rule, CMS stated that it would not make use of certified, interoperable health IT a condition of participation in Medicare, but might revisit the issue in future rulemaking. **The AHA opposes including health IT in the Medicare conditions of payment for hospitals.** The conditions of participation address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, current commercial health IT applications do not always meet hospitals' needs, and certification efforts are in their infancy. As noted in a recent report by the Agency for Healthcare Research and Quality

(AHRQ), the evidence on health IT does not yet support this level of requirement. Imposing it would amount to an unfunded mandate.[1]

TRANSPARENCY OF HEALTH CARE INFORMATION

Significant progress has been made in making quality information more transparent. The AHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with CMS and others to form the HQA. The work of the HQA has led to the voluntary reporting and sharing of 21 quality measures with the public on the *Hospital Compare* Web site, and more measures of hospital quality and patient satisfaction are planned for the future. This effort has been tremendously successful, with nearly all inpatient PPS hospitals voluntarily reporting quality information. Efforts to further expand public availability of hospital quality information must continue to be pursued through the HQA.

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. Consumers deserve meaningful information about the price of their hospital care, and hospitals are committed to sharing information that will help consumers make important decisions about their health care.

However, sharing pricing information is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service role – like fire houses and police stations – serving the essential health care needs of a community 24/7; and most hospitals cannot yet provide prices that reflect important information from other key players, such as the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals and CMS face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and

[1] "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication No 06-E006 (April 2006).

- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

We are pleased that CMS acknowledged in its FY 2007 inpatient PPS final rule the complexities involved in presenting pricing information in an accurate and useful manner, and recognized that an education effort will be required. We also are pleased that CMS plans to make pricing information available for other types of providers and services. Consumers should have information on physician services, and common procedures in hospital outpatient clinics and ambulatory surgery centers.

The AHA's position statement on hospital pricing transparency outlines steps to improve the pricing information available to consumers. We shared this information with CMS in our comments on the FY 2007 inpatient PPS proposed rule. In summary, we recommended:

- A federal requirement for states, working with state hospital associations, to expand existing efforts to make hospital charge information available to consumers.

- A federal requirement for states, working with insurers, to make available in advance of medical visits, information about an enrollee's expected out-of-pocket costs.

- A federal-led research effort to better understand what type of pricing information consumers want and would use in their health care decision-making.

- A hospital-led effort to create consumer-friendly pricing "language" – common terms, definitions and explanations to help consumers better understand the information provided.

More can and should be done to explain pricing information to consumers clearly and consistently. Hospitals will work together to create common terms, definitions and explanations of complex pricing information. HHS should provide incentives to the states to improve transparency at the state and local level, and, through AHRQ, complete research on what consumers want and would use in purchasing health care services.