American Association of
AAASC
Ambulatory Surgery Centers
P.O. Box 5271● Johnson City●TN● 37602-5271●423 915 1001● fax 423 282 9712
www.AAASC.org

1160
(2)

October 10, 2006

VIA HAND DELIVERY

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:

On behalf of the American Association of Ambulatory Surgery Centers (AAASC), 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 Federal Register, 49505, August 23, 2006). AAASC is a professional medical association of physicians, nurses, and administrators who specialize in providing surgical procedures in cost-effective outpatient environments, primarily in Medicare-certified ASCs. Most AAASC members own or operate in Medicare-certified ASCs, and so have considerable experience with and interest in the criteria utilized to determine whether a procedure is appropriate for performance within an ASC.

We appreciate the diligent work of your staff to review and evaluate the proposed changes to the ASC payment system in 2007, and understand the tremendous work that has gone into developing a new payment system for implementation in 2008. We offer the following recommendations for 2007, but also hope these recommendations will be reflected in the new payment system as well.

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

In 2007, CMS proposes to add a modest number of procedures to the ASC procedure list, and we commend the agency for continuing to update the payment system in the year preceding systemic reform mandated by the Medicare Modernization Act of 2003 (MMA). In the August 23, 2006 *Federal Register*, CMS also proposes changes to the procedure list for 2008 that substantially modify the criteria for inclusion on the ASC list. The effect of these changes will add more than 700 additional procedures to the spectrum of services that ASCs will be reimbursed for providing to Medicare beneficiaries.

Given the wholesale reform of the procedure list on the horizon for 2008, we understand the agency's desire to minimize intermediate changes that will be paid under the existing groupers for only one year. As such, the comments below focus on the changes proposed to the list of procedures approved for the ASC for 2007. We believe the modest additions proposed for 2007 mark continued improvement in beneficiaries' access to ASC services. However, we believe there are many more procedures that meet these criteria but are not proposed for addition to the list. In addition, there are many procedures that are appropriately performed in ASCs that are unnecessarily excluded from the list by the agency's existing criteria.

We will submit additional detailed comments in response to the proposed changes for 2008. However, many of the criteria used to determine which procedures are approved for ASCs in 2007 appear to serve as the foundation of the policies that will shape the procedure list in 2008. Underlying our continued objection to the criteria for additions to and deletions from the list is the principle that the physician, in consultation with the beneficiary, is best-positioned to determine the most appropriate site of service for a surgical procedure.

Until such time as the physician's judgment is the primary determinant of site of service, we believe beneficiaries will be inappropriately deprived of a high quality, lower-cost alternative surgical site. In Appendix A, we reiterate our long-standing concerns with the use of an inclusionary list of procedures that may be reimbursed when performed in an ASC and the criteria employed by the agency to approve procedures for addition to and deletion from the list. Again, we commend the agency for proposing a more robust procedure list for 2008 and look forward to working with the agency and the physician community to remove unnecessary barriers to beneficiaries' access to safe, quality surgical services.

A. Procedures Proposed for Addition to the ASC List

We commend CMS for updating the ASC list 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 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 21356, which describes the open treatment of a depressed zygomatic arch fracture. The proposed payment group assignment is Group 3 ($510). Based on a survey of ASCs, the average cost of performing this procedure in an ASC is $1,365. The Group 3 reimbursement level is insufficient to cover the resources associated with performing CPT 36818 in an ASC. The average cost of performing CPT 21356 is similar to the median HOPD cost for this procedure. According to data released with the NPRM, the median HOPD cost for CPT 21356 is $1,581.50 and the APC payment rate is $1,425.30. CPT 21356 should be in ASC payment Group 9 ($1,339).

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). The cost of the kit used at each level varies from $700 to $1,400, 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 ($1,339). 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 $1,542.47. We believe the HOPD data is a more reliable proxy for the cost of providing this service.

We are also concerned about CPT code 36818, which describes upper arm cephalic vein transposition. The proposed payment group assignment is Group 3 ($510). Based on a survey of ASCs, the average cost of performing this procedure in an ASC is $2,056. The Group 3 payment rate is insufficient to cover the resources associated with performing CPT 36818 in an ASC. The average cost of performing CPT 36818 in an ASC is similar to the median HOPD cost for this procedure. According to data released with the NPRM, the median HOPD cost for CPT 36818 is $2,089.70 and the APC payment for this service is $2,336.80. CPT 36818 should be in ASC payment group 9 ($1,339).

Finally, we are concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1,339) and Group 1 ($333), respectively. The cost of the intravascular stent averages $1,725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. Therefore, reimbursement limited to the nine payment group methodology would be insufficient to cover the device costs for these procedures. However, we believe ASCs should be eligible to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs currently experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. We therefore recommend CMS specifically direct carriers to provide separate reimbursement for L8699 when submitted with CPT codes 37205 and 37206. If this separate payment is not assured, ASCs are unlikely to perform these services.

Despite the challenges to adequate reimbursement for the procedures discussed above, we believe CMS should add the procedures to the list. All are clinically appropriate services and adding them will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

B. 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 place of service reporting can be a highly unreliable indicator of the actual site of service; significant error rates (80% and higher in some cases) for selected services have been reported (OIG Report Number A-05-04-00025). 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. There are many services that have been on the ASC list since its inception although they

technically qualify as office procedures based on the criteria currently employed by CMS. 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). CMS stated "Consistently, the physician office is the predominant service setting even though the procedures were included on the ASC list." CMS subsequently concluded "that the relative stability of the utilization and site of service is evidence that the inclusion of the codes on the ASC list has not influenced the physician's selection of setting for performance of the procedures and provides strong evidence that there is a small but consistent population of beneficiaries for whom the ASC setting is the most appropriate for these procedures."

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 be seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also leads to significant additional expense to both the program and its beneficiaries. 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 comfortable and safe 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. We believe all the CPT codes presented in Table 42 should be added to the ASC list for CY 2007.

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

Table 43 of this proposed rule presents procedures that commenters suggested for addition, but that CMS is not adding because they do not meet current clinical criteria (71 Fed. Reg. at 49629). The specific clinical criteria that form the basis for rejecting each of these procedures are not stated. We believe all of the procedures discussed below are clinically appropriate and request CMS add these procedures to the ASC list for CY 2007.

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. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. Now, these procedures are commonly performed for non-Medicare patients in the ASC setting. Although CMS has not included these procedures on the ASC list to date, CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures were being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. We recognize an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC. The policy also exposes the beneficiary to the higher coinsurance responsibility of the outpatient department.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. To our knowledge there is only one recent study on this issue. This study exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an ambulatory elective laparoscopic cholecystectomy, the surgeon's application of patient selection criteria can minimize the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient

selection criteria would make such conversions a rare occurrence.

c. 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 and with a home visit for follow-up. 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.

C. 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 on 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.

In addition to the services discussed above, we believe there are several other surgical and procedural services that are clinically appropriate additions to the ASC list and worthy of consideration. These procedures are referenced in Appendix B. We believe CMS should add these procedures to the list effective January 1, 2007.

D. Comments on the Agency's Response to May 4, 2005 Interim Final Rule

We applaud CMS for revising the ASC payment group for various procedures on the current ASC lists. These corrections help ensure that Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients by adequately reimbursing ASCs for their costs.

We are concerned, however, that the payment group assignment for CPT 51992 is still insufficient to cover the cost of performing the procedure in an ASC. The current payment group assignment is Group 5 ($717). The average cost of performing CPT 51992 in an ASC is $1,589. This average cost includes a weighted average sling cost, which was derived from a representative sample of ASCs. By using a weighted average sling cost, we are able to accurately incorporate synthetic supply costs into the payment for all procedures performed. Moreover, it is important to note that the agency incorporates synthetic supply costs when calculating the HOPD median cost for CPT 51992. The median HOPD cost is $2,510.48 and the APC payment rate is $2,678.23. CPT 51992 should be in ASC payment group 9 ($1,339).

II. Implementation of Section 5103 of Pub. L. 109-171 (DRA)

Given the absence of a correction notice, we are concerned to note CPT codes 19290 and 19291, which describe preoperative placement of a needle localization wire in the breast, are not listed in Addendum AA of the proposed rule as ASC list procedures for 2007. Both procedures are currently on the ASC list as Group 1 procedures. We believe this is a typographical error. However, if these CPT codes were omitted intentionally, we query whether they were removed from the ASC list because they are not separately reimbursed under OPPS?

If this is the case, we do not believe this action is a correct application of the DRA's statutory requirement. The purpose of Section 5103 was to prevent ASCs from being paid more than hospitals for providing the same services. There is nothing in the statute or its legislative history to indicate Congress intended to deny ASC coverage for procedures packaged under a totally different payment system. The DRA payment cap is meant to apply only to those procedures for which there is both an ASC "standard overhead amount" and an OPPS "fee schedule amount" for purposes of

comparison. If, as with 19290 and 19291, there is no OPPS fee schedule amount because the service is packaged into the APC payment, then there is no basis for making a valid payment comparison and the DRA cap does not apply.

Further, 19290 and 19291 are pre-operative localization procedures, and since the ASC payment rate for the subsequent surgery was calculated assuming separate payment for 19290 and 19291, excluding these services from the ASC list without adjusting payment for the operative procedure upward would be inappropriate. Therefore, we believe CPT codes 19290 and 19291 should remain on the ASC list for 2007.

III. 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 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. Therefore, 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:" to be followed by the currently listed outcomes (i) through (vi).

* * * * *

Thank you for considering our comments. If you have any questions or need additional information, please do not hesitate to contact our Washington representative, Marian Lowe, at (202) 626-6872.

Sincerely,

John Duggan, M.D.
President
American Association of Ambulatory Surgery Centers

CC: Leslie V. Norwalk, Esq., Deputy Administrator, CMS
Craig Jeffries, Esq., Executive Director, AAASC

Appendix A: Use of an inclusionary procedure list and 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 extensive revisions to the criteria used to determine which procedures may be reimbursed in the ASC setting are appropriate. Until such reforms are implemented, beneficiary access to ASC services will continue to be unnecessarily limited in CY 2007.

We look forward to the changes proposed for 2008 and commend the agency for using the implementation of a new payment system to likewise reform of the process for identifying procedures appropriate for the ASC. Because both the 2007 and 2008 list criteria rely on a similar set of assumptions about the safety of beneficiaries in the ASC, we reiterate two longstanding recommendations of the ASC community. We believe, as MedPAC has proposed, that moving from an inclusionary to an exclusionary procedure list will enhance beneficiaries' access to services and better synchronize the regulation of ASCs with the rapid advances in science and technology. Further, we recommend that CMS revisit the criteria it uses to assess whether a procedure should be reimbursed in an ASC.

Recommendation 1: The inclusionary procedure list should be abandoned.

Rationale:

The ASC community has objected to the use of an inclusionary list of covered ASC procedures for many years. We believe it is not 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 are performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient surgical and 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. State licensing law is an additional protection for Medicare beneficiaries.

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 insureds to ASC services. Decisions regarding the site of service are recognized to be the province of the insured's physician and state law. 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 at ASCs for privately insured patients - at significant savings to the patient and to the insurer. These and other services can and should be available to Medicare beneficiaries as they are for

commercially-insured individuals – including MedicareAdvantage patients not bound by the agency's FFS restrictions.

As it is moving toward in the 2008 rule, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and develop a list of services specifically excluded from coverage "based on clinical safety standards and whether the service requires an overnight stay." 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 their ability to safely perform the same scope of services provided in hospital outpatient departments, this list should also be used to identify procedures excluded from coverage in ASCs.

Recommendation 2: CMS should revisit its coverage policies ASC procedures.

Rationale:

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 for CY 2007 using obsolete and outdated criteria that CMS itself previously proposed to substantially revise in 1998 (63 Fed. Reg. at 32298). At that time CMS, then HCFA, stated "We propose to remove the references to "commonly performed" found in §416.65(a) and the time limits on operating, anesthesia, and recovery time that are currently spelled out in §416.65(b)(1) and (2)." Below, we discuss the policies currently employed by CMS to determine eligibility for the procedure list and offer our critique their utility.

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; many procedures have moved almost exclusively to the outpatient environment. New procedures have evolved that have never been predominantly performed in the inpatient setting. Examples include newer arthroscopic and endoscopic interventions, and surgical treatments using laser or radiofrequency instrumentation. These procedures were developed predominately in the

outpatient setting and are performed safely and cost-effectively on thousands of non-Medicare 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 surgical 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 for CY 2007. 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 regulations provide that a procedure performed 50 percent or more of the time in physician offices 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 Medicare beneficiaries in the office setting, certain 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 should be dependent on the individual patient. Even when a procedure is frequently performed in an office, there are circumstances when the office is an inappropriate or unavailable setting. There are many factors governing when a procedure is performed in a physician office. A brief summary of these key 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 maintain position 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) will be necessary, requiring instruments and cautery not available in the office.

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 to 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 large extent, this varies based upon the volume of procedures performed 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. When appropriate resources are unavailable in an office, a patient should not be arbitrarily prohibited from receiving the service in an ASC (and forced to the HOPD) simply because of arbitrary coverage criteria tied to the procedure list.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may choose to not 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 – Some state laws and regulations impose limitations on what can be done in offices. These state provisions may require specific equipment, staff or even accreditation for certain procedures. 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 included on the ASC 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" by permitting ASCs to perform procedures requiring stays of up to 24 hours.

Appendix B: Additional Codes Recommended for Inclusion on the ASC List for CY 2007

CPT Code	Descriptor
11603	Excision, malignant lesion, trunk, arms, or legs; excised diameter 2.1 to 3.0 cm
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
21390	Open treatment of orbital floor blowout fracture; periorbital approach, with alloplastic or other implant
21406	Open treatment of fracture of orbit, except blowout; without implant
21407	Open treatment of fracture of orbit, except blowout; with implant
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
28124	Partial excision bone; phalanx of toe
31620	EBUS during bronchoscopic diagnostic or therapeutic intervention(s)
35492	Transluminal peripheral artherectomy, percutaneous; iliac
35493	Transluminal peripheral artherectomy, percutaneous; femoral-popliteal
35494	Transluminal peripheral artherectomy, percutaneous; brachiocephalic trunk or branches, each vessel
35495	Transluminal peripheral artherectomy, percutaneous; tibioperoneal trunk and branches
36100	Introduction of needle or intracatheter; carotid or vertebral artery
36120	Introduction of needle or intracatheter; retrograde brachial artery
36140	Introduction of needle or intracatheter; extremity artery
36145	Introduction of needle or intracatheter; arteriovenous shunt created for dialysis
36200	Introduction of catheter, aorta
36215	Selective catheter placement, arterial system; thoracic or brachiocephalic first order
36216	Selective catheter placement, arterial system; thoracic or brachiocephalic second order
36217	Selective catheter placement, arterial system; thoracic or brachiocephalic third order
36218	Selective catheter placement, arterial system; thoracic or brachiocephalic additional second or third order
36245	Selective catheter placement, arterial system; abdominal, pelvic or lower extremity first order
36246	Selective catheter placement, arterial system; abdominal, pelvic or lower extremity second order
36247	Selective catheter placement, arterial system; abdominal, pelvic or lower extremity third order
36248	Selective catheter placement, arterial system; abdominal, pelvic or lower extremity additional second or third order
38792	Injection procedure; for identification of sentinel node

40812	Excision of lesion of mucosa and submucosal, vestibule of mouth; with simple repair
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
60210	Partial thyroid lobectomy, unilateral
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
63001	Laminectomy; cervical
63003	Laminectomy; thoracic
63005	Laminectomy; lumbar, except for spondylolisthesis
63011	Laminectomy; sacral
63020	Laminotomy; cervical
63040	Laminotomy, reexploration; cervical
63045	Laminectomy, facetectomy and foraminotomy; cervical
63048	Laminectomy, facetectomy and foraminotomy; each additional cervical, thoracic or lumbar
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)

Federation of American Hospitals®

117

FEDERATION OF AMERICAN HOSPITALS
40 Years of PROVEN LEADERSHIP
1966 - 2006

Charles N. Kahn III
President

October 10, 2006

VIA HAND DELIVERY

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

Re: ***Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payments System Annual Payment Update Program – HCAHPS Survey, SCIP, and Mortality; Proposed Rule; 71 Fed. Reg. 49506 (August 23, 2006)***

Dear Dr. McClellan:

This letter presents the comments and recommendations of the Federation of American Hospitals ("FAH") to certain aspects of the Hospital Outpatient Prospective Payment System ("OPPS") and calendar year ("CY") 2007 payment rates, and to proposals regarding reporting hospital quality data for fiscal year ("FY") 2008 Inpatient Prospective Payment System ("IPPS") Annual Payment Update Program, which were published by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on August 23, 2006 (the "proposed rule").

The Federation of American Hospitals is the national representative of privately owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. The FAH greatly appreciates the opportunity to comment on CMS' proposed rule regarding the outpatient prospective payment system updates, and new proposals regarding reporting hospital quality data for FY 2008 inpatient prospective payment system updates.

I. GENERAL COMMENTS – HOSPITAL QUALITY DATA

The FAH consistently supports high quality patient care, regardless of whether such care is delivered in inpatient or outpatient settings. The FAH has been a leader in engaging its hospital members to report their quality performance since October 2003. In addition, as a founding and active member of the Hospital Quality Alliance (HQA), the FAH continues to support multiple CMS efforts to improve hospital quality and safety. Our organization's goal is to help build a national hospital quality reporting system that provides standardized, useful information to public and private payors, patients and their families, regulatory and accrediting bodies, and other stakeholders in the health care delivery system.

While the FAH has been in the forefront of those supporting quality reporting and enhancement processes, the FAH nonetheless believes that in this case, CMS is seeking to implement reporting measures and standards for outpatient services that, in part, may not be best suited for improving quality of care in the outpatient setting. In some cases, the proposed rule seeks to apply inappropriate measures and standards to the outpatient setting. More importantly, the FAH believes CMS would exceed its authority if it tied Medicare payment to the reporting of such measures and standards in the outpatient setting without additional legislation. Finally, with respect to the quality reporting measures proposed by CMS for the fiscal year 2008 inpatient PPS program, FAH supports CMS' efforts in this area. However, the FAH suggests that some additional clarifications be made in the final rule with respect to how some of these future measures will be implemented.

II. OPPS QUALITY REPORTING REQUIREMENTS FOR CY 2007

A. Inappropriateness of Using Current (FY 2007) Inpatient Quality Measures as Proxy Measures for Quality Assessment in the Outpatient Setting.

CMS, in the past, has stated that it intends to use only those quality measures that have been endorsed by the National Quality Forum (NQF) as national standards. The quality measures that are currently required for hospitals participating in the Inpatient Prospective Payment Systems (IPPS) under Medicare were developed, at least most recently, under a mandate imposed by the Deficit Reduction Act of 2005 (DRA) [Pub.L. 109-171]. These 21 quality measures, now required for IPPS hospitals under the DRA, as of October 1, 2006, have been endorsed by NQF as national standards, and are fully supported by the Hospital Quality Alliance (of which CMS and FAH are members).

Now, however, CMS has asked for public comment on the appropriateness of using these 21 hospital-based inpatient quality measures for judging and assessing health care delivery in the outpatient setting. Moreover, CMS has proposed tying these 21 quality measures to hospitals' payments under OPPS. The FAH believes it is premature for CMS to apply these measures in the outpatient setting. CMS should consider that the NQF has endorsed these 21 quality measures as national standards for *inpatient hospital care only*; NQF has not endorsed these measures for use in the outpatient setting.

The 21 IPPS quality measures relate to treatment for heart attack, heart failure, pneumonia and surgical care. Some of the measures now required under IPPS, may turn out to

be relevant and appropriate for measuring quality in the outpatient setting, at least for some patients. However, many of these quality measures principally concern, and were developed to assess, care in the inpatient setting. At this point, there has been no thorough and scientific review of the application of these IPPS measures to care provided in the outpatient setting. Before CMS considers adopting these measures for the outpatient setting, a thorough and scientific review of the measures should be conducted by NQF in order to make this determination.

Once the NQF endorses quality metrics for hospital outpatient services, CMS should then ask the newly created AQA-HQA Steering Committee (which CMS co-chairs) as the "privately led organization or alliance" (*see* 71 Fed. Reg. 49670 of the proposed rule) to reach a working consensus regarding which measures hospitals and physicians should collect and report for OPPS purposes. Only then should CMS propose an outpatient quality reporting program.

In an effort to move expeditiously, CMS appears to have taken a short cut that could undermine the very purpose of measuring health care provider performance. Measuring quality performance should be, first and foremost, about improving the care that is provided. If a measure does not fit well with the setting in which such care is provided, it is more than likely not an appropriate measure, and it becomes merely a "paper exercise" solely linked to payment without any real intent or ability to improve patient care.

The FAH supports CMS' vision in considering a quality reporting program for the outpatient setting, and appreciates CMS' commitment to encouraging participation in this process by a privately led organization or alliance. But the system will be better served in the long run, for all parties involved, including patients, if the program evolves through the same process that has worked so successfully to promote the inpatient quality reporting program. To reach this goal, a little more time is necessary than the abbreviated approach envisioned in the proposed rule.

B. CMS is Exceeding its Authority to Construct An OPPS Quality Reporting Program.

Under the proposed outpatient quality reporting program, CMS would tie a hospital's outpatient PPS payments to the facility's reporting performance for inpatient hospital measures. CMS bases its authority to tie outpatient payments to quality reporting on selected provisions of the Medicare statute that has never before been used for this purpose. First, CMS cites a subsection of 42 U.S.C. § 1395l (Social Security Act § 1833) regarding "Prospective Payment System for Hospital Outpatient Department Services" under the heading "System Requirements." In particular, the Medicare Act provides that "the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass through payments under paragraph (6), and *other adjustments as determined to be necessary* to ensure equitable payments, such as adjustments for certain classes of hospitals." *See* 42 U.S.C. § 1395l(t)(2)(E) (Social Security Act § 1833(t)(2)(E)).

CMS cites the clause "other adjustments as determined to be necessary" as its authority to implement hospital quality reporting measures tied to outpatient service reimbursement in the proposed OPPS rule. Specifically, CMS appears to be contending that the denial of a full market

basket adjustment as a result of a hospital's failure to comply with quality reporting requirements constitutes a type of payment "adjustment" under the OPPS that is deemed "necessary to ensure equitable payments." The FAH respectfully disagrees and questions whether CMS can realistically base its authority to tie OPPS payments to hospital quality reporting measures on this statutory language regarding "adjustments."

Under the terms stated in the proposed OPPS rule, denial of a full payment based on failure to comply with the OPPS proposed quality measure reporting requirement is far more accurately characterized as a "penalty" than as an "adjustment." In addition, when one considers that outpatient providers otherwise are entitled to the payment update but for their potential non-compliance with the quality reporting rules, it also becomes questionable whether this penalty even results in ensuring that payments are "equitable." When one considers further that, as discussed above, the application of inpatient measures to the outpatient setting does not necessarily establish an appropriate nexus to quality; it becomes even clearer that the proposed payment reduction under OPPS constitutes a payment penalty rather than an adjustment to ensure that payments are "equitable."

Notably, the U.S. Court of Appeals for the District of Columbia Circuit has considered the definition of "equitable payments" under this authority. (*See Amgen v. Smith*, 357 F.3d 103 (D.C. Cir. 2004).) The appeals court was clear in its decision that an "adjustment" is distinctly different than a policy that represents a significant departure from, or a restructuring of, an entire statutory scheme. A payment penalty for failure to report quality data is more akin to a restructuring of a payment system to create a completely different model as opposed to a payment adjustment that redistributes federal funding "equitably" among providers based on substantive policies.

The FAH also notes that the statutory language authorizing adjustments to outpatient service reimbursement is modified by a requirement for budget neutrality. This is important because there appears to be no mechanism under the proposed OPPS payment "penalty" system to return money withheld from one provider (due to the failure to comply with a quality measure reporting requirement) to the system (for distribution to some other outpatient provider) to ensure overall budget neutrality under OPPS. While a similar argument could be mounted with respect to outlier and transitional pass through adjustments, those items are clearly dependent on patient related issues completely outside of a hospital's control (unlike the quality reporting system) and can therefore more accurately be described as "adjustments" as opposed to "penalties." In contrast, the quality measure reporting requirement is not tied to any patient related issues outside of a hospital's control, and thus constitutes a "penalty" imposed on a hospital for failing to act in a way that CMS wants to require it to.

Finally, Congress has demonstrated that it understands how to link payment to quality as was stated clearly first in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and again in the Deficit Reduction Act of 2005 (DRA) with respect to inpatient quality measures. Congress could easily have done the same for outpatient services, but did not. CMS's attempt to "extract" OPPS authority from Congress' specific statement on IPPS quality measure reporting is not reasonably supportable under established principles of statutory construction.

Accordingly, the FAH believes that the proposed OPPS rule denying full payment updates to outpatient providers for failure to comply with quality reporting requirements does not fit within the language of a cited statutory authority, Section 1395l(t)(2)(E).

Moreover, CMS appears to be similarly overreaching if it intends to rely on 42 U.S.C. ¶ 1395l(t)(2)(F) as an alternative basis for linking full payment updates to quality data reporting. This latter provision states "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services." (42 U.S.C. § 1395l(t)(2)(F) (Social Security Act § 1833(t)(2)(F)). As the FAH understands it, quality data reporting has no direct relationship with the **volume** of outpatient services. In fact, there appears to be no specific link between the two. As such, it is difficult for the FAH to understand how denying a full payment update based on quality data reporting standards would or can control unnecessary increases in the volume of covered outpatient services. Therefore, the FAH believes that it is an unsupportable stretch for CMS to contend that the penalty for not meeting the quality data reporting standards is somehow a method of controlling the volume of covered outpatient services.

C. Unfairness of the Penalty.

The FAH also believes that the payment "penalty" tied to hospital quality data reporting requirements is inherently unfair. Hospitals that do not pass their validation tests to receive their full update beginning October 1, 2006, on the basis of IPPS quality data reporting, will receive a 2% reduction in their market basket payment update under IPPS. This is appropriately supported under Section 5001 of the DRA. But under the proposed rule, and unbeknownst to such hospitals at the time, they now stand to be penalized again in the future based on the same validation results, when such validation results are applied to the hospital's outpatient services and outpatient payment under OPPS. As we discussed above, such redundant application was never contemplated under the DRA or anywhere else in the governing Medicare statute. Moreover, if applied to the outpatient context, it effectively results in retroactive rulemaking, which is not permissible action for a federal agency unless expressly allowed by Congress, which is not the case here.

D. Value Based Purchasing Program and OPPS.

In the proposed rule, CMS indicates that it plans to include outpatient services in its DRA mandated report on implementation of a "value based purchasing program" by fiscal year 2009. CMS states, in pertinent part:

> Our ultimate goal is implementation of an OPPS RHQDAPU program that extends to all hospital outpatient departments that are paid under the OPPS, that is based on a set of quality and cost of care reporting measures that are specific to the hospital outpatient setting, and that is appropriately aligned with developments in quality reporting and value based purchasing in other payment systems such as the IPPS. We will take into consideration issues related to the appropriate alignment of quality and cost of care reporting and value based purchasing under the IPPS and the OPPS during the planning process mandated by Section 5001(b) of the

> DRA for implementation of inpatient value based purchasing by FY 2009. We plan to include all hospital services, whether inpatient or outpatient, in a report on implementation of value based purchasing.

See 71 Fed. Reg. 49670.

The FAH believes that a comprehensive, systematic approach to quality is ultimately a laudable and achievable goal. The FAH believes further that a quality measure reporting system for both inpatient and outpatient services, if properly designed, is fully consistent with a comprehensive and systematic approach, and will ultimately provide more comprehensive information about the quality of services provided by all hospitals across all treatment settings.

However, the FAH is concerned as well that CMS must hew to existing Congressional authority for purposes of designing such programs. In reviewing the applicable provisions of the DRA, and the DRA mandated report on implementation on a value based purchasing program under DRA § 5001(b), the FAH notes that this law was specific to inpatient PPS hospitals, and makes absolutely no mention of services provided under the OPPS. In addition, as CMS itself notes in the proposed rule, some hospitals that provide OPPS services may not actually be IPPS hospitals. Thus, there are additional issues regarding CMS' authority to implement a value based purchasing program, taking into account outpatient service issues under the DRA, which have not been adequately addressed in the proposed rule.

The FAH believes that Congress should first be asked to provide such authority and guidance. In the interim, the FAH believes that CMS should follow existing, well functioning processes to seek and encourage industry stakeholder participation and consideration of how best to implement an outpatient value based purchasing program.

III. PROPOSED QUALITY MEASURES FOR FISCAL YEAR 2008 INPATIENT PPS PROGRAM.

The proposed fiscal year 2008 quality measures contained in the proposed rule are those that have been discussed, reviewed and supported by HQA. The FAH fully supports CMS' continued recognition of the importance of considering the consensus views of a wide range of stakeholders. HQA represents a balance of public and private payors, employers, consumers, providers, accreditors, and others, and the FAH hopes that CMS will continue to consider the consensus views of HQA in the future as it progresses to implement additional quality reporting provisions contained in the Deficit Reduction Act (Section 5001(a)) [Public Law 109-171].

The FAH does, however, request clarification on a few issues which it hopes CMS will consider prior to publishing the final rule.

A. HCAHPS Methodology Issues.

CMS proposes to expand the scope of its quality reporting and improvement programs by including the HCAHPS ("Hospital Consumer Assessment of Healthcare Providers and Systems") patient perspectives of care survey. FAH, along with other members of the HQA, have been supportive of this initiative for several years. Areas where we seek clarifications are listed below.

1. Public Disclosure of Mode Experiment Results.

The FAH requests that CMS make public the results of its mode experiment which was conducted to determine how survey responses differ based on how the survey is conducted. We understand that CMS plans to weight the survey results on the findings from this study. The FAH requests, therefore, that the study findings, the methodology used for calculating and determining the weighting formulas, and the actual algorisms and calculations, be made public throughout this process.

2. Hospitals Required to Collect HCAHPS Data.

The proposed rule states that hospitals will be required to submit HCAHPS data to the QIO clinical warehouse beginning with discharges that occur in the third calendar quarter of 2007 (July through September discharges). In order to meet this HCAHPS requirement for the RHQDAPU program, CMS proposes that all hospitals, including those hospitals new to HCAHPS, and hospitals that have been collecting data since October 1, 2006, "submit a formal pledge to CMS by July 1, 2007 stating that they will collect and submit HCAHPS data to the QIO clinical warehouse starting with July 2007 discharges." CMS then states that "all hospitals must submit this pledge to CMS."

The HCAHPS requirements are tied to satisfying the requirements of the RHQDAPU program for fiscal year 2008. The FAH is assuming that the words "all hospitals" (with reference to which facilities must submit a pledge) refers to all hospitals eligible for payment under the RHQDAPU program, but not to other hospitals that are not covered by the RHQDAPU program. The FAH asks CMS to clarify whether the FAH's assumptions are correct.

With respect to those hospitals that are required to submit a formal pledge regarding their participation in HCAHPS by July 1, 2007, the FAH notes that although it was not addressed in this proposed rule, CMS has in the past required hospitals to submit an annual formal pledge form regarding their participation in the RHQDAPU program. The FAH strongly recommends that hospitals be required to submit only one pledge form each year in connection with the RHQDAPU program (which can include a pledge to participate in HCAHPS) and not multiple pledge forms. Furthermore, the FAH recommends that hospitals be permitted to submit their respective pledge electronically, among other submission options.

3. Reporting HCAHPS Results for Multi-Campus Hospitals.

CMS notes that hospitals which share Medicare provider numbers currently combine their clinical data across campuses for submission and publication of this data. CMS states that its current plan for HCAHPS is for these data also to be combined across campuses.

CMS nonetheless indicates that it is considering ways in which data could potentially be displayed by individual hospital rather than by Medicare provider number. As a starting point, CMS indicates that it is striving to identify those hospitals which share Medicare provider numbers; CMS believes this would potentially allow it to denote that on the Hospital Compare website that specific measures are comprised of multiple campuses' data.

The FAH recommends that all publicly reported hospital data be treated consistently; both clinical quality and HCAHPS data should either be reported by Medicare provider number or by individual hospital.

IV. HEALTH INFORMATION TECHNOLOGY

CMS requests comments about the role of information technology ("IT") and how CMS can encourage adoption of health IT through this proposed rule. CMS also notes the role of the American Health Information Community ("AHIC"). The FAH strongly supports the role of AHIC in determining how to promote health IT and interoperability among providers. The FAH also strongly urges CMS to consider the discussions and recommendations of AHIC, and those of other relevant, consensus-based public-private partnerships, such as the AQA-HQA Steering Committee created by HHS Secretary Leavitt, before acting. There is no question about the potential for health IT to facilitate improvements in the quality and efficiency of health care services. However, health IT can also involve significant investments on the part of the hospital community and other stakeholders in the health care industry. Therefore, uniform standards for health IT should be encouraged and adopted prudently so that the investments lead to real improvements in quality and efficiency.

In general, the FAH believes that hospitals should base their investment in health IT on their respective specific business models as they do with any other input, such as labor or plant. At this point of its development, the most valuable role that government can play is to facilitate the setting of standards for electronic health records and interoperability. To this end, we believe AHIC can play a critical role in jump starting the development of effective health IT. It is premature to consider embedding health IT in the design of any value-based purchasing program. Well-designed value-based purchasing programs should reward hospitals and other providers on the basis of their performance rather than on the use of certain inputs that are only in a nascent state of development.

While FAH supports the notion that hospitals should use health IT that is certified by the Secretary and the Certification Commission for Health Information Technology (CCHIT), it does not believe that using such technology should be part of a Medicare Condition of Participation. Again, the underlying issues of providing quality care and delivering value should not be dependent on particular inputs but rather the end result of the larger hospital system. CMS should provide incentives to hospitals to produce high quality and efficient care rather than dictate how such care is achieved. As uniform interoperability standards become available and reliable, and the price of technology implementation declines, hospitals will clearly understand the economic benefits of appropriate technology adoption. This market process should be permitted to develop before government intervenes in a heavy handed regulatory manner.

In addition to developing the technical specifications of health IT, the government should also do what it can to promote the adoption of IT in the health care industry. In this regard, the FAH believes that HHS has taken steps in the right direction to promote adoption of health IT by promulgating regulatory protections under both the physician self-referral law and the Anti-Kickback Statute for donations related to electronic health records. While improvements to those policies could be made, their promulgation reflected HHS's important leadership upon realizing that such fraud and abuse protections are necessary in order to improve the quality of care and reduce medical errors through increased adoption and use of health IT.

V. HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE.

The proposed rule describes a comprehensive national transparency initiative that CMS and the Department of Health and Human Services will undertake starting in 2006. Although the proposed rule offers some detail regarding the structure of this transparency initiative, CMS does not mention the AQA-HQA Steering Committee, a group comprised of public and private sector stakeholders which is chaired by CMS and the Agency for Healthcare Research and Quality (AHRQ). The Secretary of Health and Human Services has designated the joint steering committee to oversee the development of a national initiative to provide consumers more comprehensive information on the quality and cost of care.

The FAH strongly supports the role of this steering committee, and believes that the AQA-HQA Steering Committee is the most appropriate vehicle for representing all stakeholders' points of view that should and need to be considered in developing this national transparency initiative. The FAH believes further that such an initiative should strive to create a system whereby all stakeholders have access to uniform and standardized information on provider quality and other types of information that may develop under the initiative.

VI. Proposed Updates Affecting OPPS Payments for CY 2007

- **Proposed recalibration of "APC Relative Weights" for CY 2007, 49514 -49532**

The FAH commends CMS for its continued attempts to identify additional methods to create single APC claims and approves of the use of the "pseudo" single process, including the bypass list and the criteria. The FAH approves of the use of the process of bypassing the codes in table 1 in order to create "pseudo" single claims and approves of the use of the line-item costs associated with the bypass codes for the creation of the APCs into which the bypass codes are assigned. Again, the FAH commends CMS on continuing to develop techniques that allow the use of more claim data to set payment rates.

While the FAH agrees in general principal with CMS' proposal to exclude claims with token charges, we are concerned about exclusion of claims containing multiple surgical or cardiac catheterization lab services. CMS has allowed providers to report multiple procedures performed in the same session with a single charge under the revenue code (e.g. 360) that

describes where the procedures were performed on the same line with one of the surgical procedure HCPCS codes and the other procedure HCPCS codes with the same revenue code but with zero or token charges on the subsequent charge lines. While many of these claims may be excluded in the recalibration process due to multiple APCs on the claim, there may also be claims with a single paid APC and one or more packaged surgical procedures in the same revenue center. For instance, a cardiac catheterization procedure requires the reporting of multiple CPT codes to describe the procedure performed and generally all but one of the CPT codes is packaged. Since CMS allows OPPS hospitals to report multiple surgical services with a single charge amount and the additional charge lines are allowed to have zero or token charges, the FAH does not believe it is appropriate to eliminate these claims in the rate setting process.

We believe that CMS must use claims that have a token or zero charge present when the token or zero charge is associated with a revenue code on the claim that is repeated and only one charge line for the revenue code has a charge greater than $1.01 and only one charge line for the revenue code is paid by APC. This will help ensure that CMS uses all appropriate single APC claims and packages all appropriate charges when establishing payment rates for services which require the reporting of multiple CPT codes in order to describe the procedure. The FAH supports the elimination of claims containing token or zero charge lines for all other scenarios.

CMS has proposed to revise the CCR calculation to make the computation consistent between the methodology used by fiscal intermediaries and the methodology used by CMS to model OPPS. Specifically, CMS has proposed to revise the CCR calculation to remove allied health costs and to make the CCR calculation more specific to OPPS by weighting by Medicare Part B charges from Worksheet D, Parts V and VI. FAH supports the proposed changes to make the computations consistent and more accurate.

- **Proposed Changes to "Packaged Services", 49533-43537**

"We are proposing to accept the APC Panel's recommendation and pay separately for CPT codes 36540, 36600, 38792, 75893, 94762, and 96523 when any of these codes appear on a claim with no separately payable OPPS services also reported for the same date of service."

We commend CMS for their continued attempts to identify packaged CPT codes that describe procedures that can be provided to patients as the sole service on a given date, and for recognizing the significant hospital resources utilized when providing these services. We agree with the CMS proposal to pay separately for CPT codes 36540, 36600, 38792, 75893, 94762, and 96523, and appreciate CMS's willingness to gather claims data and review CPT codes with the packaging subcommittee. We urge CMS to finalize this proposal.

- **Proposed Payment for Partial Hospitalization**

The FAH has been provided a copy of an analysis completed by The Lewin Group on behalf of the National Association of Psychiatric Health Services (NAPHS) and its members in

response to the continued Medicare partial hospitalization rate reductions, which declined by over 12% in 2006 and which CMS is proposing to further reduce by another 15% in 2007.

As identified in the Lewin analysis, the FAH believes it is critical to use the hospital specific cost-center for partial hospitalization instead of the overall outpatient CCR because partial hospitalization is a highly unique outpatient hospital service. More specifically, physicians are required to certify that a patient would require inpatient psychiatric care in the absence of treatment in the partial hospitalization program. Similarly, according to CMS program memorandum, a partial hospitalization program for Medicare purposes is a comprehensive, structured program that uses a multidisciplinary team to provide comprehensive, coordinated services within an individual treatment plan to individuals diagnosed with one or more psychiatric diagnoses. In addition, due to the unique character of a partial hospitalization program compared to other hospital outpatient services, the payment unit is a per diem payment. The partial hospitalization APC 0033 is the only APC in the entire outpatient PPS that utilizes a per diem as the unit of payment.

CMS should be concerned that the major purpose of the partial hospitalization benefit to either divert patients from inpatient treatment or to move patients more quickly out of the hospital and into a less restrictive structured program is being hampered by the payment reductions. Hospital-based programs are uniquely situated to provide patients with continuity of care and to move them when medically appropriate to a lower level of care. This will result in lower inpatient psychiatric expenditures under Medicare and would be consistent with the inpatient psychiatric prospective payment system, which encourages shorter length of stays.

The Lewin Group analysis has raised a very critical issue regarding the appropriateness of using the overall hospital outpatient CCR instead of the specific cost-center for partial hospitalization. According to the Lewin report, "it is possible that a more accurate CCR for PHP services is available on the cost reports than the CCR that is being utilized by CMS in its calculation. However, it is likely that isolating a more appropriate CCR is difficult giving the variability in reporting across hospitals with regard to where they enter their PHP CCR on the cost report and what term they used to describe the partial hospitalization program." More specifically, based on the Lewin Group analysis, a simple median of the specific cost-center for partial hospitalization is 0.43, while the simple median outpatient (overall) CCR is 0.29 – or a 48% CCR differential from the CMS calculation.

The Lewin Group analysis on cost-to-charge ratios did not include CMHC data because, while the Provider Specific File contains CCR data for CMHCs, CMHC cost reports are not represented in the electronic HCRIS data available from CMS, which was used in the Lewin analysis. However, FAH believes that the same dynamic that occurs with the hospital-based partial hospitalization programs regarding the need to focus on the hospital specific cost-center, which would have a higher CCR than the overall outpatient CCR, would be the case with CMHCs. This is based on the fact that the CMHC partial hospitalization program is the only service covered by Medicare in a CMHC and that this service (PHP) has to meet a hospital-level medical intensity to be covered. Therefore, it can be assumed that other CMHC services would have a lower medical intensity consistent with their overall mission. With CMS using these less

intensive services in the CCR calculation, this methodology would tend to dilute the PHP CCR, thereby understating the CMHC median partial hospital cost.

As a result, the FAH recommendations for the Partial Hospitalization APC include:

1. At a minimum, CMS should freeze the PHP rate at CY2006 level of $245.91.

2. CMS should undertake an in-depth analysis to determine the feasibility of using the more accurate hospital-specific PHP cost-center for purposes of determining future rates.

3. However, in light of the significant median CCR understatement of 48% noted within the Lewin analysis, the FAH believes it would be appropriate to increase the 2006 PHP rate by the 3.4% market basket update and utilize the resulting per diem amount for the 2007 PHP rate while CMS completes the recommended in-depth analysis.

- **Proposed Wage Index Changes for CY 2007 ("OPPS Wage Indices") 49539 - 49541**

The FAH generally supports CMS's decision to adopt the IPPS wage indices for OPPS payments. However, the FAH has significant concerns about the application of a 100% occupational mix adjustment for 2007, which was imposed in the Bellevue Hosp. Ctr. V. Leavitt court order. We refer CMS to our Occupational Mix comment letter dated June 12, 2006 for details related to these concerns and recommendations. Specifically, the FAH strongly encourages CMS to approach Congress for authority to transition the occupational mix and to repeal the mandate that CMS apply an occupational mix adjustment to hospital wage indices.

- **Proposed CY 2007 Hospital Outpatient "Outlier Payments", 49546-49547**

CMS has proposed to calculate the fixed-dollar outlier threshold for CY 2007 by using the same methodology as used in CY 2006 except the overall CCR calculation has been proposed to be revised to align the computations by the fiscal intermediaries and CMS to model OPPS. As stated above, FAH supports the proposed revision to the overall CCR calculation.

For CY 2007, CMS has proposed to continue to use the "charge methodology" as was used in CY 2006. FAH made extensive comments in our letter dated June 12, 2006 to the proposed IPPS rule for FY 2006 on the need to revise the charge methodology for the decline in the CCR. FAH refers CMS to those comments for consideration. In a letter dated June 12, 2006, MedPAC made similar comments on the need to revise the charge methodology for the decline in the CCR. In the final IPPS rule published in the Federal Register on August 18, 2006, CMS agreed that the charge methodology needed to be revised to account for the decline in the CCR.

"Nevertheless, we now agree with the commenters that it is appropriate to apply an adjustment factor to the CCRs so that the CCRs we are using in our simulation more closely reflect the CCRs that will be used in FY 2007."

FAH recommends that CMS modify the charge methodology used to set the OPPS outlier threshold to account for the decline in the CCR in a manner similar to that used for IPPS.

In the proposed rule CMS does not disclose the estimated outlier payments for CY 2005. CMS states "At this time, we do not have a complete set of CY 2005 claims in order to produce this number for CY 2005". CMS goes on to state that it will report the estimated payments in the final rule. FAH encourages CMS to publish an estimate of outlier payments in the proposed rule using the available claims data to permit the public to better comment on the outlier policy.

VII. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

- **"Medication Therapy Management Services" 49563**

"Medication therapy management services are not new services in the OPPS, as they have been provided to patients by hospitals in the past as components of a wide variety of services provided by hospitals, including clinic and emergency room visits, procedures, and diagnostic tests. As such, we believe their associated hospital resource costs are already incorporated into the OPPS payments for these other services that are based on historical hospital claims data. The three Category III CPT codes specifically describe medication therapy management services provided by a pharmacist. We have no need to distinguish medication therapy management services provided by a pharmacist in a hospital from medication therapy management services provided by other hospital staff, as the OPPS only makes payments for services provided incident to physicians' services."

The FAH disagrees with the CMS decision to not create new APC codes for MTMS and to not accept the APC Panel's recommendations to create three new APC codes for payment. The APC Panel further recommended that these new codes should be implemented in CY 2007 and CMS should provide guidance to hospitals on how and when these codes should be reported.

Recent published information shows that historical hospital claims data does <u>not</u> include associated hospital resource costs for medication therapy management services and therefore payment for MTMS is not incorporated into the current OPPS payments.

A 2004 survey showed that 69% of all health systems had <u>no</u> pharmacists routinely involved in ambulatory care. Of the 31% involved, less than 50% had involvement in the provision of MTMS services. Further, of the 16% of health systems who reported pharmacist involvement in MTMS services, these health systems rarely provided these

services to all outpatients of the facility.[1] A survey conducted in 2005 showed only 3.5% of U.S. hospitals had a pharmacist assigned to the Emergency Room for any period of time.[2]

Since these services are not reflected in historical claims data, new APC codes should be established with instruction to hospitals to report these services under revenue code 940-Other Therapeutic Services, as recommended by the APC Panel at their March 2006 meeting.

MMA 2003 defined a medication therapy management program that is provided to targeted beneficiaries. Targeted beneficiaries are described as Part D eligible individuals who—

(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure), and,
(II) are taking multiple covered Part D drugs.

The CDC has defined the following as chronic diseases and conditions: Arthritis, Asthma & Allergies, Cancer, Chronic Fatigue Syndrome, Diabetes, Epilepsy, Heart Disease[3], Hemochromatosis, Hepatitis B, Hepatitis C, Iron Overload, Osteoporosis, Overweight and Obesity, and Stroke.[4]

Some chronic diseases require intense medication monitoring for patient compliance, drug-drug interactions, adverse effects, and therapeutic thresholds. These chronic diseases should be included in MTMS for a first-year benefit to allow CMS to examine the impact of MTMS on quality of care. These medication intensive chronic diseases are Asthma, Cancer, Diabetes, Epilepsy, Heart Disease and Stroke. A National Coverage Determination could be established to limit MTMS services to certain medical conditions.

We urge CMS to recognize these codes and make payment for 0115T under new technology APC 1494 and 0116T and 0117T under new technology APC 1493.

- **"Radiology Procedures" (APCs 033, 0662, and Other Imaging APCs), 49567**

---

[1] Knapp KK, Okamotoa MP, and Black BL. ASHP survey of ambulatory care pharmacy practice in health systems---2004. *Am J Health-Syst Pharm.* 2005: 62:274-84

[2] Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings-Dispensing and Administration- 2005. *Am J Health-Syst Pharm.* 2006; 63:327-45.

[3] CDC website. Heart Disease includes: coronary heart disease, heart attack, angina, acute coronary syndrome, aortic aneurysm and dissection, arrhythmias, cardiomyopathy, congenital heart disease, heart failure, peripheral arterial disease, and rheumatic heart disease. http://www.cdc.gov/HeartDisease/about.htm (October 2, 2006)

[4] CDC website. http://www.cdc.gov/node.do/id/0900f3ec8000e035 (September 10, 2006)

The FAH commends CMS' proposed plan to continue to delay any discount for multiple imaging procedures. Any cost economies of performing multiple procedures in the same "family" of imaging procedures by imaging modality and contiguous body parts are currently reflected in the hospital costs that are used to establish the payment weights for these procedures. Because the APC weights are calculated based on the hospital's charges reduced to cost by the facility cost to charge ratio, the APC payment weights already reflect a lower payment rate for any cost savings by the facility. OPPS radiological procedures, whether performed as individual radiological services or in multiples, already receive an average payment rate that accounts for any cost savings when the services are performed in multiples. This averaging is appropriate and desirable in a prospective payment system. The alternative is a micro-managed payment system that resembles the cost-based reimbursement system that Congress discarded in favor of a bundled PPS. Since the payment for radiological services already captures any cost savings associated with performing multiple radiologic services in the same session, the FAH opposes any further reduction to radiologic services.

Additionally, the payment calculation for the technical component of radiologic services paid under the physician fee schedule (MPFS) is based on specific PE inputs of clinical labor, supplies and equipment for each service. The MPFS calculation does not take into account the averaging of costs that is inherent in the OPPS. We believe it is inappropriate to apply the same methodology used for the physician fee schedule payments to the OPPS. The FAH strongly urges CMS to not just delay application of a discounting policy to OPPS but to abandon such discounting as unneeded and unwarranted for OPPS since discounting has already been considered in setting APC weights.

VIII. Proposed OPPS Payment Changes for Devices, 49568 – 49580

- **Proposed Treatment of "Device-Dependent APCs"**

"Packaging the costs of the intraoperative electrophysiologic testing of the ICD leads yields many more single bills on which to set median costs and also increases the median costs for APCs 0106, 0107, 0108, and 0418. Therefore, we are proposing to package CPT codes 93640 and 93641 for CY 2007."

The FAH commends the CMS for their continued efforts to analyze and establish appropriate payment for device dependent procedures such as APC 107 and 108. We encourage the CMS to continue their efforts and data analysis. We support the packaging of CPT codes 93640 and 93641 and recommend CMS finalize this proposal for CY2007.

"It would provide for a reduction in the APC payment rate when we determine that the device is replaced without cost to the provider or beneficiary or when the provider receives full credit for the cost of a replaced device... We believe that the averaging nature of the calculation of the amount of the adjustment causes it to be appropriately applied to cases of credit for the replaced device, regardless of whether there is a residual cost due to the implantation of a more expensive device."

The FAH supports the CMS' decision to reduce the APC payment for device dependent procedures when the device has been replaced by the manufacturer. However, we do not support a reduction of 100% of the estimated device portion of the APC. We do not believe that the averaging nature of the device offset calculation will allow appropriate payment to the hospital when a more expensive device is used for a beneficiary. Additionally, the charges reported by hospitals for a device include the cost of the device, handling and acquisition costs, and other overhead and administrative costs. In the scenario where a device is replaced without cost to the hospital, there are still handling and acquisition costs and other administrative costs specific to device replacements and warranty issues that the hospital incurs. If the patient receives a more expensive device then the costs to the facility are even more. The FAH is concerned that removing 100% of the calculated device costs from the APC could create such a financial burden on hospitals that beneficiary access to these critical procedures could be limited. We strongly recommend that CMS consider a reduction methodology that would allow recognition and payment of the acquisition and administrative costs associated with the device. The FAH would support a reduction equal to 70 - 80% of the calculated device portion of the APC as a method to recognize these associated costs and ensure continued beneficiary access to these important procedures.

IX. Proposed OPPS Payment Change for Drugs, Biologicals, and Radiopharmaceuticals

- **Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status, 49582-49595**

➢ **"OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"**

"Therefore, for CY2007, we are proposing to pay separately for drugs, biologicals, and radiopharmaceuticals whose per day cost exceeds $55 and packaging the cost of drugs, biologicals and radiopharmaceuticals whose per day cost is less than or equal to $55 into the procedures with which they are billed."

The CMS has proposed to continue separate APC payment for drugs, biologicals, and radiopharmaceuticals with a per day cost exceeding $55. However, the APC Panel recommended to the CMS in their August meeting to pay separately for all HCPCS coded drugs. The FAH does not support the separate payment of all drugs. The FAH believes that paying separately for all HCPCS coded drugs would be inconsistent with OPPS packaging principles and could increase hospitals' administrative burden. The FAH is also concerned about the potential negative impact to payments for other services if all HCPCS coded drugs are paid separately since the impact to the total OPPS payments must be budget neutral. The FAH urges CMS to remain consistent with the principles of a prospective payment system and carefully evaluate the overall impact of drug packaging on all hospitals.

In addition, we disagree with the utilization of the Producer Price Index (PPI) for prescription preparations as an appropriate Index for the packaging threshold adjustment. The Producer Price Index for prescription preparations includes all prescription medications, many of which are not covered under Part B benefits such as self-administrable medications.

Consequently, this Price Index does not fairly represent an inflationary index for medications covered under Part B benefits.

We recommend that as an alternative, CMS review the current ASP data that is utilized in setting rates for Part B drugs on a quarterly basis and calculate an inflationary index from the data self-reported to CMS directly by pharmaceutical manufacturers. On an annual basis, this inflationary index could be applied and the packaging threshold readjusted to accommodate inflation for Medicare Part B drugs.

"Therefore, for CY 2007, we are proposing a policy of paying for the acquisition and overhead costs of separately paid drugs and biologicals at a combined rate of ASP+5 percent".

The FAH strongly urges CMS to continue ASP+6% reimbursement for hospital outpatient Areas similar to the physician office schedule in CY2007.

The FAH believes that the changes to drug reimbursement proposed by CMS (from ASP+6% to ASP+5%) could have a detrimental effect on the ability of hospital outpatient departments and ambulatory clinics to provide the level of patient care needed by Medicare beneficiaries.

This proposed reimbursement formula (ASP+5%) is inadequate to cover handling costs of drugs reimbursed under the HOPPS. In an April 2006 GAO report, "Medicare Hospital Pharmaceuticals,"[5] small hospitals paid 1.4% more for drugs than larger hospitals and nonteaching hospitals paid 3.2% more for drugs than teaching hospitals. Previously, MedPAC's report submitted to Congress in June 2005 noted that pharmacy services and handling costs were "not insignificant" and that they "made up 26-28% of pharmacy departments' direct costs." Small, rural hospitals, particularly, may need to limit or eliminate the treatment of patients in outpatient settings due to the reduction in drug payments.

Physician reimbursement for CY2007 will be maintained at ASP+6% for the identical drug products if administered in a physician's office. If payment is lowered under OPPS to ASP+5%, this is in contradiction to the CMS goal statement, "to get rid of inadvertent incentives that favor one setting over another". The FAH strongly urges CMS to reconsider MedPAC's findings that overhead and related expenses are not insignificant at 26% to 28% of pharmacy direct costs and CMS should consider paying accordingly. At a minimum CMS should not lower the payment to ASP+5% but should continue ASP+6% reimbursement for Hospital Outpatient Areas similar to the physician office schedule in CY2007.

"...proposing for CY 2007 is to establish prospective payment rates for separately payable radiopharmaceuticals using mean costs derived from the CY 2005 claims data ..."

---

[5] GAO-06-372 Medicare Hospital Pharmaceuticals. http://www.gao.gov/new.items/d06372.pdf (August 18, 2006)

The FAH commends CMS for its proposal to establish prospective payment rates for separately payable radiopharmaceuticals using mean costs derived from the CY 2005 claims data, where the costs are determined using standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges and defaulting to hospital-specific overall CCRs only if appropriate departmental CCRs are unavailable.

The FAH urges CMS to allow hospitals to use all available HCPCS codes for drugs. Currently, CMS has assigned status indicator "B" to HCPCS codes for drug products that have multiple HCPCS codes describing different dosages of the same product. The FAH does not believe there is any valid reason to continue to restrict providers to use of only one HCPCS code (generally the smallest dose) when multiple codes are available. In addition this creates an administrative burden to providers who must report different HCPCS and billing units for Medicare. Examples of these drugs are: Gamma Globulin (J1460 – J1560), Capecitabine (J8520, J8521), Cyclophosphamide (J9070 – J9092) Cyclophosphamide lyophilized (J9093 – J9097), Dacarbazine (J9130, J9140), Etoposide (J9181, J9182), Methotrexate Sodium (J9250, J9260), Mitomycin (J9280 - J9291), and Vincristine Sulfate (J9370 - J9380). The FAH urges CMS to allow providers to use all of these HCPCS codes to report these drug products instead of restricting us to only the HCPCS code with the lowest dose descriptor.

X. Proposed Brachytherapy Source Payment Changes "OPPS: Brachytherapy", 49597 – 49599

"We are proposing to pay separately for each of the sources listed in Table 29 below on a prospective basis for CY 2007, with payment rates to be determined using the CY 2005 claims-based median cost per source for each brachytherapy device. ...we are proposing that the cost of brachytherapy sources be subject to the outlier provisions of section 1833(t)(5) of the Act. ...Because brachytherapy sources would no longer be paid on the basis of their charges reduced to cost, we are proposing to discontinue our use of payment status indicator "H" for APCs assigned to brachytherapy sources. We are proposing to use status indicator "K" for all brachytherapy source APCs for CY 2007."

The FAH commends CMS for continuing to pay separately for brachytherapy sources and for basing payment on the source-specific median costs for brachytherapy sources as reflected in the 2005 claims data instead of on the basis of their charges reduced to costs. FAH also appreciates the payment being made on a "per source" basis rather than a "per day" basis in recognition of the high variability of treatment costs among providers. Because brachytherapy sources are subject to coinsurance, we also commend CMS for proposing to assign these sources to status indicator "K" instead of status indicator "H".

However, the FAH disagrees with the CMS proposal that the cost of the brachytherapy source would be subject to the outlier provision of OPPS. Historically, brachytherapy sources have not been subject to additional outlier payment. Additionally, services assigned to status indicator "K" have not been eligible for outlier payment for the last 2 years. It is burdensome to providers and others attempting to estimate payment to constantly vary the services that are used in the outlier calculation. It is also difficult to base

the outlier calculation not only by status indicator, but also by APC code within a status indicator. We believe that the brachytherapy sources should be treated like separately paid drugs and pass though devices and be excluded from the outlier calculation. We urge CMS to either continue to exclude brachytherapy sources along with the other services assigned to status indicator "K" from the outlier calculation, or to assign brachytherapy sources to a new status indicator.

XI. Proposed Changes to "OPPS Drug Administration" Coding and Payment for CY 2007, 49599 – 49604

"...we are proposing to continue the CY 2006 OPPS drug administration coding structure, which combines CPT codes with several C-codes...we are proposing that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other OPPS services."

The FAH commends CMS for lifting the special requirements for modifier 59 for specific drug administration services and allowing facilities to apply modifier 59 to drug administration services using the correct coding principles that are used for all other OPPS services. However, the FAH strongly recommends that CMS discontinue using the 2006 OPPS drug administration coding structure which combines CPT codes and HCPCS level II codes. We urge CMS to transition to the full set of drug administration CPT codes in CY 2007 to eliminate the administrative burden on hospitals created by the use of the drug administration HCPCS level II "C" codes for Medicare only and CPT codes for other payers. The FAH recommends CMS finalize the six proposed drug administration APCs and crosswalk them to the 2007 CPT codes for drug administration.

"For CY 2007, the APC Panel also recommended that CMS reevaluate payment for IVIG administration, especially considering the resource intensity of IVIG infusions. We are accepting this APC Panel recommendation and believe that our proposed CY 2007 drug administration payment policy that would provide specific payment for each hour of infusion would provide more accurate and appropriate payment for lengthy infusions, including the administration of IVIG. IVIG administration in the outpatient hospital setting typically occurs over 3-6 hours, and under our proposal hospitals would receive separate payment for the first hour of infusion, along with payments for each of the additional 2-5 hours generally required for the IVIG infusion. Considerable hospital resources are used throughout the infusion period, including significant clinical staff time to monitor and adjust infusions based on patients' evolving conditions, so we believe separate payment for each additional hour is appropriate. With respect to separate payment for IVIG preadministration-related services, the APC Panel recommended that CMS maintain separate payment as long as it remains appropriate. For CY 2006 only, we created the temporary G-code G0332 (Preadministration-related services for intravenous infusion of immunoglobulin, per infusion encounter). We are accepting this APC Panel recommendation and have considered whether separate payment for IVIG preadministration-related services remains appropriate. Based upon our ongoing review of the IVIG marketplace and our CY 2007 proposed payment policies for items and services under the OPPS, we believe that separate payment for

preadministration-related services specific to IVIG infusions would not be necessary in CY 2007 to ensure Medicare beneficiary access to IVIG."

The FAH urges the CMS to ensure that IVIG payment rates do not decrease and to continue payment of preadministration fees (G0332) pending the results from two studies currently underway. One study is being performed by the HHS Assistant Secretary for Planning Evaluation (ASPE) to better understand the market for IVIG and elevated access and reimbursement concerns for patient and physicians. The second study, requested by House Committees on Commerce and Ways and Means, is underway by the OIG and specifically is evaluating IVIG access and pricing. Both studies are due out later this year.[6]

IVIG ASP data reported to CMS does not reflect the actual purchase price paid by the hospital (that provides the service to the patient), therefore an ASP-based reimbursement methodology for IVIG is flawed. Bruce Steinwald, Director, Health Care, for the U.S. Government Accountability Office, provided testimony to the House Committee on Ways and Means on July 13, 2006 and acknowledged that, "CMS does not instruct manufacturers to provide a breakdown of price and volume data by purchaser type; that is, by physicians, hospitals and other health care providers, and by wholesalers, which purchase drugs for resale to health care providers. As a result, CMS cannot determine how well the average price data represent actual acquisition costs for different purchaser types. In particular, to the extent that some of the sales are to wholesalers that subsequently mark up manufacturers' prices in their sales to providers, the ASP representation of provider acquisition cost is attenuated."[7]

In fact, unlike most other drugs, hospital outpatient departments, irrespective of size, are unable to purchase IVIG directly from the manufacturer. Typically, manufacturers sell IVIG to secondary "specialty" wholesalers who carry a variety of blood products, and items in short supply. Manufacturers report to CMS the average sales price (ASP) to these wholesalers. These wholesalers, in turn, mark-up the IVIG products resulting in a higher cost to the hospital than what is being reported to CMS. In addition, all manufacturers of IVIG have placed limitations on the quantity per month that an individual hospital is "allocated" via the wholesaler based upon historical purchases. Any additional purchases are often purchased "off-contract" at more than twice the original contract price. In some instances, hospitals are unable to purchase IVIG over their allocation at any price. One major manufacturer recently reduced the "allocation" for an entire pharmacy buying group from 88% of historical purchases to 60%. Hospitals are required to receive, and are invoiced for, their entire monthly allotment in one shipment. This places an additional financial burden on the hospital to pay for product outside of normal purchasing patterns.

---

[6]U.S. House Committee on Ways and Means, July 13, 2006, http://waysandmeans.house.gov/hearings.asp?formmode=printfriendly&id=5304#Kuhn (October 3, 2006)

[7]U.S. House Committee on Ways and Means, July 13, 2006, http://waysandmeans.house.gov/hearings.asp?formmode=printfriendly&id=5304#Kuhn (October 3, 2006)

Hospital charges for IVIG are typically not adjusted to reflect individual IVIG product price changes, because of the frequency of price variations for each IVIG shipment. Hospital charges for IVIG are established based on an average hospital cost and therefore, do not adequately reflect the actual cost of the IVIG product when the hospital must buy "off-contract". Therefore hospital claims data does not adequately reflect the actual cost of IVIG.

According to the ASHP drug shortage website, (August 3, 2006)[8], three IVIG products have been discontinued by the manufacturer and the remaining 5 manufacturers are listed in short supply. Reasons for the shortage are listed as, "manufacturers will not provide a reason."

There is a significant decline in reimbursement for IVIG and associated drug administration payments in the 2007 proposed rule when compared to rates as of July 1, 2006. For example, a hospital administering 24 grams of IVIG (lyophilized) in a 3 hour infusion to an outpatient would receive $1370.77 in reimbursement under rates effective July 1, 2006. However, under the proposed 2007 rule, this payment will decrease to $1222.32 even with the proposed change to pay each hour of infusion separately.

The FAH urges the CMS to ensure that IVIG payment rates do not decrease and to continue payment of preadministration fees (G0332) pending results of these two studies underway by the HHS ASPE and OIG. The FAH strongly recommends that CMS apply alternative mechanisms for determination of the reimbursement schedule of IVIG products due to the inadequacy of the ASP in reflecting the actual price paid by the hospital to the wholesaler for IVIG products. Alternative reimbursement schedules are permitted under current statute, and were requested in a letter dated May 11, 2006 from 58 members of the U.S. House of Representatives to HHS Secretary Leavitt.[9]

XII. Proposed Hospital Coding and Payments for "Visits", 49604 - 49618

"While we do not yet have a formal set of guidelines that we believe may be appropriately applied nationally to report different levels of hospital clinic and emergency department visit and to report critical care services, we have made significant progress in developing potential guidelines and, therefore, are proposing for CY 2007 the establishment of HCPCS codes to describe hospital clinic and emergency department visits and critical care services."

The FAH strongly urges CMS to make no changes relative to the coding of clinic and emergency department visits until national guidelines for reporting facility resources for clinic and emergency department visits are finalized. Although the FAH desires the establishment of codes to describe clinic, emergency department and critical care services by hospitals, implementing a new coding structure without guidelines would be premature and

---

[8] ASHP website. http://www.ashp.org/shortage/bulletin.cfm?cfid=17654878&CFToken=49520897&id=20 (August 18, 2006)

[9] Letter, Congress of the United States. Restore Access to IVIG for Medicare Patients, May 11, 2006. http://www.fffenterprises.com/web_files/ivig_public_hlth.pdf (August 18, 2006)

could lead to confusion and inappropriate coding. We urge CMS to delay all coding changes until the national standards are ready.

"...for CY 2007 we are proposing a set of five G-codes for use by all entities that meet the definition of a DED under the EMTALA regulations in § 489.24 but that are not Type A emergency departments, as described in Table 33 below. These codes will be called 'Type B emergency visit codes'."

While the FAH understands the different emergency department definitions as defined by CPT and requirements related to EMTALA definition of dedicated emergency departments, we are concerned with the creation of two sets of HCPCS codes to differentiate payment for these services. The FAH does not support development of additional codes to allow for payment differences. We strongly recommend CMS find another methodology to pay appropriately for these services.

"Therefore, we are proposing five payment levels for clinic and emergency visits and one payment level for critical care services."

The FAH strongly opposes any changes relative to the APC payment structure for clinic and emergency department visits prior to the issuance of national E/M visit guidelines. Changes to the APC structure for E/M visits impact not only the visit codes but also the APC relative weights for all OPPS services since all APC relative payment weights are scaled against a mid level clinic visit. This type of change can create confusion and is particularly troublesome when CMS acknowledges that "If future data indicate that three payment levels are more appropriate, [CMS]... may revert back to three payment levels." Changes from 3 APC payment levels to 5 APC payment levels when CMS is still unsure what coding structure will be finalized is premature and difficult for hospitals to manage. Additionally, it is our understanding that one of the reasons the AHA AHIMA Expert Panel recommended only 3 coding levels for hospital visits is that it is very difficult to appropriately define and differentiate between 5 levels of care. The differentiation in care on a 3 level system provides a system that is less subjective and more definitive.

The FAH strongly urges CMS to make no changes to E/M visit coding and APC payment structure until national guidelines are published.

XIII. Proposed OPPS Payment for "OPPS: Observation Services", 49620-49621

We recommend that CMS consider the Observation Subcommittee of the APC Advisory Panel's recommendation (August 23-24, 2006) on adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.

We also recommend that CMS consider the Observation Subcommittee's recommendation (August 23-24, 2006) of performing claims and data analysis to allow CMS to consider revising criteria for separately payable observation services when certain procedures that are assigned status indicator T (e.g. insertion of bladder catheter or laceration repair) are reported on the same claim with a emergency department visit and observation

services, and all other criteria for separate observation payment (e.g. qualifying diagnosis code, number of hours, etc.) are met.

XIV. Medicare Contracting Reform Mandate, 49659-49665

- **CMS' Vision for Medicare Fee-for-Service and MACs, 49660**

"MACs will be the providers' primary contact with Medicare, and CMS will hold the MACs accountable for overall provider and beneficiary satisfaction and correct claims payment."

The FAH is pleased CMS will hold the MACs accountable for provider satisfaction. However, the FAH encourages CMS to include providers beyond just input on MAC performance requirements and standards. Providers have the potential to be severely impacted by competitively awarded contractors that are not meeting their performance obligations. Therefore, the FAH strongly recommends that providers be given the opportunity to participate in the contractor selection, review, and renewal process.

The FAH also urges CMS to consider the ability and availability of the potential contractor to meet the needs of the providers assigned to the MAC. For example, the MAC should be available during normal hospital business office hours regardless of the hospital's location within the jurisdiction.

"With respect to financial management, as was required of intermediaries and carriers, MACs will promote the fiscal integrity of the program and be accountable stewards of the Medicare Trust Fund dollars. The MACs will be required to pay claims timely, accurately, and in a reliable manner while promoting cost efficiency and the delivery of maximum value to the program."

The FAH commends CMS for their requirement for MACs to pay claims timely. However, we strongly recommend that CMS not allow a MAC to move to a less frequent payment schedule. We believe Medicare claim volumes across the industry continue to warrant the most frequent payment schedule feasible.

- **Provisions of the Proposed Regulations 49662-49664**
  - **Assignments of Providers and Suppliers to MACs 49662-49664**

"Large chain providers comprised of individual providers that were formerly permitted by CMS to "nominate" an intermediary, which we refer to as "qualified chain providers," will be permitted to request 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."

While the FAH appreciates CMS' willingness to address consolidation for large chain providers, we believe that qualified chain providers that would otherwise operate in many MAC jurisdictions should be allowed to consolidate into a fewer number of MACs but

greater than just that of the home office. There may be instances in which it will be more efficient for the chain provider, the MAC and CMS for all the chain's hospitals within a particular MAC's jurisdiction to be served by the local MAC rather than the chain's single MAC status where the home office may be located in a different MAC.

If a chain were to consolidate to just one MAC, there is the potential for an excessive workload for a MAC which may have in its jurisdiction many home offices for large chain organizations seeking CMS designated single MAC status. Therefore, CMS should consider alternate ways, such as allowing the chain to select multiple MACs so that the MAC workload would be more efficiently distributed among several MACs. This would assist CMS in achieving Congress' goal for a more efficient Medicare operation by more equally distributing the work load for a large chain rather than adding a substantial amount to a single MAC and still bringing legitimate business value to the large chain provider. The chosen MACs could be those in the local jurisdiction where the chain's providers reside. For example, if a chain had a large number of hospitals in Florida and its home office was in another state, the chain could choose to leave its Florida hospitals in the Florida jurisdiction and the remainder of its hospitals in its home state.

In addition, while consolidating all of a chain's hospitals into one MAC may bring legitimate business value to the chain, if the MAC has a problem with its systems or is having other problems paying claims, this could be very detrimental to the chain provider.

Also, the LCD policy that governs the MAC where the hospital is located may be different than the LCD for the MAC where the chain's home office is located. This creates a potential situation where the local physician bills for a service that is covered under the local MAC's LCD but is not covered by the hospital's home office MAC. It is illogical for the hospital to be put in this position of having to incur expenses for non-covered services for the hospital, but covered for the physician, especially when it is the physician who has the sole authority and responsibility to order medically necessary care because the local physician will bill through the local MAC for the MAC where the hospital is located. This situation is exacerbated by the fact that the typical chain organization often operates multiple types of entities, such as hospitals, freestanding imaging centers, and physician offices.

For these reasons, FAH recommends that even if a chain organization may have single MAC status, CMS should permit all of the chain's hospitals that are geographically located within the jurisdiction of a particular MAC to remain with that local MAC rather than migrate to the chain's home office. In such circumstances, the chain would retain its single MAC status, but CMS would recognize that there are clearly instances in which a local MAC that does not serve the chain's home office would be better suited to serve all of the chain's entities located within that MAC.

Another chain-related issue has to do with the process for converting the chain's entities to the home office MAC should the chain seek and be granted single-MAC status. Details on that process need to be spelled out as soon as possible. For example, the MAC for Jurisdiction 3 will soon be in operation and the hospitals located in that MAC will be expected to convert to the new MAC in the foreseeable future. However, if the hospital belongs to a chain organization which expects to seek and receive designation as a single MAC, and the MAC for the chain's home office is in another jurisdiction and has not yet been selected (or is otherwise not yet in operation), the hospital is in the position of having to convert its operations twice – once to adjust to the new local MAC and again to adjust to the chain's home office MAC. Clearly, this is an inefficient and unwise resource use not just for the hospital, but also for the MAC and CMS.

FAH recommends therefore, that such a hospital be permitted to remain with its current FI, assuming the FI is still operating, until such time as the chain's home office MAC has been selected and is operational. This would obviate the expenses associated with two systems conversions.

The FAH requests clarification from CMS as to whether the granting of single-MAC status to a large chain providers can be retracted at the request of the home office. That is, the home office can elect to remove its providers from single-MAC status and have providers be serviced by their local MAC. Because chain providers organizations frequently change in size and scope of operations, such as the establishment of a regional central business office (CBO) to handle billing and collection operations, it may determine that it is more efficient to work under a local MAC rather than retain the single-MAC status. In addition, a converse situation might exist where the a large chain might find significant benefits of converting from a local MAC setup to single-MAC status. The FAH recommends this option of converting from or to single-MAC status be permitted each fiscal year with a minimum required notice period of at least one hundred (120) days before the start of the next home office cost reporting period, with the effective date to be with the start of the next provider cost reporting period.

"We are proposing to incorporate a definition of "qualified chain provider." The criteria that constitute the proposed definition of a "qualified chain provider" mirror the elements that were historically applied."

The FAH strongly recommends that the definition of a "qualified chain provider" also include otherwise ineligible providers when they are part of a qualified chain. Based on the current definition in the proposal, qualified chain providers (for example, hospitals, SNFs, and CAHs) may consolidate to a single MAC but ineligible providers (for example, physicians, IDTFs) that are part of the same chain must use the MAC in their local jurisdiction. Allowing otherwise ineligible providers to consolidate to the MAC of their qualified chain provider would facilitate integration of important functions such as coverage rules, provider education, and support for beneficiaries. Variations in coverage rules between the hospitals of a chain provider and physicians that are part of that chain could cause confusion over the coverage of the service not only among providers but also with Medicare beneficiaries, and could result in the need for multiple

editing criteria within the systems of the chain provider. Allowing this consolidation could also minimize confusion for Medicare beneficiaries who have questions about their encounter information including follow-up on denials.

* * * *

FAH appreciates CMS's review and careful consideration of the comments in this letter, and would be happy to meet, at your convenience, to discuss them. If you have any questions, please feel free to contact Steve Speil, Senior Vice President at 202-624-1529.

Respectfully submitted,