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ASC COALITION

September 14, 2007

VIA HAND DELIVERY

Acting Administrator Kerry Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P - Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Weems:

On behalf of the undersigned members of the ambulatory surgical center (ASC) community, please accept the following comments regarding changes proposed for the ASC and hospital outpatient prospective payment systems (OPPS) for Calendar Year 2008 in 72 Fed. Reg. 148 (August 2, 2007). These comments are submitted by a diverse coalition of national and state associations and companies representing all types of ASCs – single- and multi-specialty, physician owned, joint ventures between hospitals and physicians, and joint ventures between physicians and management companies. These facilities range from the very small to the very large and are located in all parts of the nation.

At the outset, we would like to commend the Centers for Medicare and Medicaid Services for the careful consideration and effort that has gone into developing the new ASC payment system for implementation in 2008. The final rule implementing a new payment system for ASCs (CMS-1517-F) made significant strides towards aligning the ASC and hospital outpatient department (HOPD) payment systems. We want to thank CMS for linking the rule-making process for hospital outpatient departments and ASCs as well.

We commend you for making a number of changes between the proposed and final rule implementing the ASC payment reform that result in better alignment between the two payments systems. One such example is allowing ASCs to bill for certain ancillary services separately payable under the OPPS. This alignment will also help to mitigate the unnecessary movement of procedures from the ASC back into the HOPD at a cost to both the government and Medicare beneficiaries. However, we remain concerned that CMS did not adopt a set of policies that would result in a fixed relationship between ASC and HOPD payment over time. CMS's goal should be a payment system that facilitates Medicare beneficiaries' ability to understand their real costs in alternative settings and their ability to make direct comparisons.

The ASC Coalition also appreciates the agency's recognition that budget neutrality in the new payment system should be assessed by looking at the universe of outpatient surgical services across all three ambulatory settings. We strongly disagree with the agency's assessment that the migration of procedures currently on the ASC list into and out of the ASC setting will result in no net change in Medicare expenditures. Because many procedures currently on the ASC list are rarely performed in ASCs because the payment rates are too low to cover the cost of providing them, we believe the migration of procedures into the ASC from the HOPD will greatly exceed that of any migration that increases costs to the Medicare program. As a result, our analysis showed that budget neutrality was most likely to be achieved when the conversion factor is 73 percent of the HOPD one. Further, we are concerned that CMS underestimated the volume of migration of certain procedures from the ASC to the more expensive hospital setting that will occur when payments are about 35 percent less than the OPPS rates. By using these incorrect migration estimates CMS has underestimated the payment rate for ASCs at which budget neutrality will be achieved. The resulting rates, paying ASCs 65 percent of HOPD payments, are inadequate and will have a dramatic impact on payments for some of the most common ASC procedures. These low rates may result in physicians moving cases to the more expensive hospital setting, increasing the costs borne by Medicare beneficiaries and the government rather than the savings that could have been achieved.

The low ASC conversion factor may have a profound effect on many procedures negatively affected under the revised ASC payment system. For example, gastroenterology procedures, many of which are commonly performed in the ASC setting would experience significant rate reductions. It would be extremely difficult for single specialty gastroenterology ASC—or any other facility focused on a narrow range of services negatively impacted by the new system—to alter their case mix. These facilities represent an extension of the physicians' practices into which substantial capital investments for equipment and an appropriate physical plant have been made. Additionally, many certificate-of-need states narrowly specify the use of the facility, not allowing for a change in case mix. The magnitude of the negative financial impact on such facilities may have undesired consequences on Medicare beneficiary access, particularly for the already underutilized screening colonoscopy benefit. We urge the agency to use their broad statutory authority to mitigate the potential adverse effect on access to services.

Finally, we commend CMS for deciding not to implement ASC reporting of quality measures prior to January 1, 2009. We anticipate ASC quality measures will be endorsed by the National Quality Forum (NQF) by the end of this year. By 2009, the congressionally mandated implementation date, nationally endorsed measures specific to ASC facilities will be available. The ASC Quality Collaboration, a collaborative group of ASC stakeholders, is working to ensure that ASC quality data is appropriately developed and reported and has spearheaded the development of quality measures now pending before the NQF. Its members include ASC companies, associations, physician societies, accrediting bodies and government entities.

The major goal of any change in Medicare ASC payment policy should be to expand Medicare beneficiaries' access to high quality, cost effective surgical care. In the comments that follow, we share our views on how existing access can be preserved and expanded.

OVERVIEW

In its final rule issued in August, the agency took advantage of its broad statutory authority to design a new ASC payment system. Although tying ASC payment to the payment system already established for

OPPS brings the latter's imperfections to the ASC setting, the Coalition believes that the OPPS represents a reasonable proxy for the relative cost of procedures performed in the ASC. For many of the procedures newly eligible for payment in the ASC, the reimbursement that will be available under the fully implemented payment system will provide an economically viable alternative, allowing beneficiaries to receive services outside the hospital. However, certain individual and classes of surgical services will not become, or will no longer be, economically viable in the ASC. In general, our comments below address procedures disadvantaged by provisions in the final ASC or proposed ASC/HOPD rule that, notwithstanding provisions in these rules, could be safely and efficiently performed in the ASC.

We reiterate our comments of last November that three core principles should drive policies for the ASC payment system. The policies should:

- Ensure meaningful beneficiary access to the wide range of surgical procedures that can be safely and efficiently performed in the ASC;
- Provide fair and reasonable payment rates to allow beneficiaries and the Medicare program to save money on procedures that can be safely performed at a lower cost in the ASC, rather than in the HOPD; and
- Align the ASC and HOPD payment systems to the maximum extent possible to provide Medicare beneficiaries with greater price transparency and eliminate distortions between the payment systems.

1. Ensuring Beneficiaries' Access to Services

Medicare beneficiaries have diverse needs for the type and complexity of surgical services offered in outpatient settings. Ensuring that beneficiaries receive their surgical care in the setting best suited to their medical needs, as determined by their physician in consultation with the patient and their family, should be the primary objective of ambulatory surgery payment policies.

We support the expansion of access to a large number of new procedures in the ASC setting. This will offer convenience and access to Medicare beneficiaries. At the same time, we believe that this expansion can and should be carried further to include a number of other surgical procedures appropriate for the ASC setting. However, CMS policies would limit a physician's ability to determine the appropriate site of service because it does not allow payment for many surgical procedures that are clinically appropriate in the ASC.

2. Establishing Reasonable Reimbursement Rates

We believe that the payment system for ASCs can and should achieve the following policy goals, discussed in more detail in the sections that follow:

- Achieve savings to the Medicare program and its beneficiaries;
- Promote payment neutrality across sites of service delivery and competition among surgical service providers; and
- Encourage increased transparency of information on Medicare providers.

3. Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and HOPDs will enhance the transparency of the cost of obtaining surgical care in different settings, thus allowing Medicare beneficiaries to make better choices

regarding their surgical care. While we appreciate that the revised payment system moves towards consistency between the ASC and HOPD systems, there are several instances in which alignment of the ASC and HOPD payment systems is incomplete or inconsistent. In particular, we draw your attention to the following inconsistencies.

DISCUSSION

A. Covered Procedures

We are pleased that in the final rule, CMS has moved toward the recommendations of the Medicare Payment Advisory Commission's (MedPAC) March 2004 Report to the Congress. We do not believe the agency's rule fully embraces the policies articulated by the Commission. We fully support MedPAC's recommendation and CMS's stated view that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from payment of an ASC facility fee. This use of an exclusionary, rather than inclusionary, list allows Medicare beneficiaries access to the broader range of the ASC services that are currently safely offered to non-Medicare patients. Further, as new procedures are developed, Medicare beneficiaries are more likely to be assured timely access to these technological advances in ambulatory surgical care.

B. Criteria for Excluding Procedures

The ASC Coalition supports MedPAC's recommendations for reforming the ASC procedure list as described above. Instead, CMS plans to implement criteria for excluding procedures from the ASC setting will result in continued barriers to beneficiaries' access to the broad spectrum of services that can be safely and efficiently performed in an ASC. The ASC Coalition believes the additional criteria CMS finalized are unnecessary. CMS uses three criteria to determine which procedures required inpatient care: 1) the invasive nature of the procedure, 2) the need for at least 24 hours of post-operative recovery time or monitoring before the patient can be safely discharged, or 3) the underlying physical condition of the patient. These standards remain in place today and are used to distinguish non-covered inpatient services from covered outpatient services. We continue to believe that the same criteria applied to determine which procedures are excluded from the outpatient setting in hospitals should be used to determine procedures excluded from payment in ASCs.

Given that the wording and intent of the exclusionary guidelines under OPPS parallel those under the ASC payment system, it is not necessary to have different language determine the exclusions for outpatient surgery. Rather than maintaining two separate sets of criteria for defining appropriate outpatient surgery, CMS should apply one uniform set of standards. The OPPS standards have proven sufficient to safeguard patients in the hospital outpatient setting and therefore can be reasonably applied to the ASC setting. We believe that physicians should, in consultation with their patients, retain the ability to determine the site of service for a given procedure.

Under this rule, CMS proposes to exclude from ASC payment in 2008 a number of procedures payable under the OPPS, but has not provided any rationale for the exclusions. It also should include a requirement that if CMS proposes a procedure for exclusion from ASC coverage (other than procedures on the inpatient list), the agency must specify the clinical basis for exclusion, with the data it relied on and supporting arguments, and then provide the industry with an opportunity to respond with its own data, arguments and medical experts with ASC experience. As a general rule, a procedure should not be excluded from ASC coverage if it can be safely performed in an outpatient surgical setting pursuant to

reasonable and generally accepted patient selection criteria, which are best applied by physicians applying their medical judgment, rather than CMS erring on the side of exclusion.

It is essential that ASCs have the opportunity to understand the basis on which CMS deems procedures to meet the criteria for exclusion from the ASC list. Without this information, our opportunity to meaningfully comment on the government's proposal is impaired. Appendix C contains procedures that are currently safely performed in ASCs without an overnight stay that CMS has excluded from the ASC list. We strongly urge CMS to reconsider these procedures. We are eager to discuss these procedures and our experiences performing them with CMS.

Definition of Surgical Procedure. We are pleased that CMS expanded the definition to include certain categories of procedures as recommended by the Coalition. We support CMS's decision to allow payment for a number of covered ancillary services when they are furnished on the same day as a covered surgical procedure and are integral to the performance of that procedure in the ASC setting including certain radiology and other ancillary services. We appreciate the addition of 29 interventional radiology codes to the ASC list of payable procedures. However, we continue to believe that any X-ray, fluoroscopy, or ultrasound procedures described within the range of CPT Category I codes that the AMA defines as "radiology" that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice should be payable in ASC setting due to their invasive nature.

Overnight Stay. We support CMS's elimination of the four-hour recovery time limit when determining what procedures should be payable in ASC setting. However, in adopting midnight as the defining measure of an overnight stay, the final rule implements a coverage standard that is at odds with the growing number of states that have expanded the concept of "ambulatory" surgery over the past 20 years by permitting ASCs to perform procedures involving stays of up to 23 or 24 hours.[1]

CMS has stated three reasons for its selection of midnight as the defining measure of an overnight stay. The first is that a patient's location at midnight is a generally accepted standard for determining his or her status as a hospital inpatient or skilled nursing facility patient, and that therefore CMS believes this concept is reasonably applied to the ASC setting. These generally accepted standards were in fact created by CMS to facilitate its regulation of inpatient hospitals and skilled nursing facilities. The patient's location at midnight is used in the inpatient hospital setting as the basis for census counting for hospital cost reporting purposes. In the case of skilled nursing facilities, midnight provides a specific reference point in time for situations involving interrupted stays and consolidated billing. These are *inpatient* settings and the processes being regulated under the midnight concept in these cases are *administrative* ones. We are not aware of any other manner in which CMS has historically used the concept of midnight and in no case in the past has CMS employed midnight in defining a clinical coverage policy.

[1] We are aware of at least 14 states that permit ASCs to retain patients for up to 23 or 24 hours of overnight recovery care: Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah. A number of states also permit stays beyond 24 hours in separately licensed or certified recovery care units.

As we have stated in previous comments, midnight may be useful for administrative functions such establishing clear billing guidelines or taking a patient census, but midnight has no clinical significance. On the other hand, length of stay is clinically meaningful and relevant to standard medical practice. In coverage policies elsewhere, CMS has defined a clinically appropriate length of stay, most notably its definition of an appropriate postoperative recovery period for the hospital outpatient department. In this *outpatient* setting, CMS excludes from coverage those procedures for which there is the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Length of stay should be a guiding principle in establishing coverage policies for ASCs as well.

In asking whether a procedure would require active medical monitoring and care at midnight, one would have to know when the procedure began in order to make a reasonable determination. Taken alone, midnight has no clinical significance. It is only when considered *in relation to another time* that midnight acquires any clinical relevance. Thus, consideration of length of stay is implicitly and inextricably part of the decision-making process confronting CMS clinical staff and medical advisors making determinations regarding ASC coverage exclusions. CMS should make that length of stay explicit in its coverage policies for ASCs, rather than basing policy on an arbitrary time of day.

The second reason CMS states for using midnight as the defining measure of an overnight stay is that overnight care is not within the scope of ASC services for which Medicare makes payment. ASCs have sought clarification regarding overnight care in the past. Neither midnight nor any other specified times have ever been included in CMS's policy clarifications regarding this matter. Rather, CMS has previously responded by referencing length of stay. In correspondence to the Federated Ambulatory Surgery Association dated May 18, 2005, CMS states that an overnight stay is a planned stay of over 24 hours and conversely that when the "length of stay is less than 24 hours, it is not considered an overnight stay." Adopting midnight as the defining measure of overnight stay is therefore also at odds with previous CMS statements, which providers have viewed as definitive and upon which they have structured their clinical operations.

The final reason CMS provides for implementing midnight as its definition of overnight stay is that midnight is straightforward and easily understood. Though this is true, it is not persuasive, particularly since the more appropriate concept of length of stay is just as straightforward and easily understood, in addition to being clinically relevant.

We are extremely troubled by a recent agency proposal that apparently would prohibit a Medicare-certified ASC from performing *any* procedures -- including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, *even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed.*

More specifically, in the August 31, 2007 proposed modifications to the ASC conditions for coverage ("CfC"), an ASC is defined as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay" – that is, recovery which requires active monitoring beyond midnight, "regardless of whether it is provided in the

ASC."[2] While we intend to submit extensive comments on the CfC proposed rule, it should be noted that this particular proposal seems to reflect a radical departure from longstanding Medicare policy, which currently allows overnight stays for non-Medicare patients, either in the ASC itself or in a separate recovery care unit, where such stays are permitted under state law. In reliance on the current policy, ASCs throughout the country have invested significant time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule. There is no apparent reason for the substantial harm and disruption that would occur from overriding state licensure laws and extending this coverage limitation to non-Medicare patients through the CfC definition of an ASC.

Unlisted Codes. The final rule excludes unlisted surgical procedure codes from ASC payment under the revised ASC payment system. This policy, in addition to being incongruent with the approach CMS takes to reimbursement of unlisted codes under OPPS, is unnecessarily restrictive. CMS has indicated that, due to a lack of specific procedural descriptions, it is not possible to determine whether such procedures would pose safety risks to Medicare beneficiaries.

In our comments on the August 2006 proposed rule, we noted the existence of several subsections of the CPT manual in which all the specific CPT codes within the clinical grouping are payable in the ASC setting. In these instances, such as procedures on the posterior segment of the eye, we argued that the unlisted codes for such sections would not reasonably pose a safety risk. In response, CMS has indicated that without knowing the specific procedure, it is not possible to evaluate whether the procedure performed would have been excluded from ASC payment due to established safety criteria. In particular, CMS has stated that it would not be able to determine whether the procedure in question involved major blood vessels, major or prolonged invasion of body cavities, or extensive blood loss, or was emergent or life-threatening in nature.

Although unlisted surgical CPT codes do not allow reporting of specific procedures, they do allow reporting of the anatomic region of the procedure. This anatomic location is sometimes quite precisely defined. In some instances, unlisted codes also identify a specific surgical technique or a specific medical condition. Knowing the anatomic location, and occasionally the surgical technique and medical condition for which the procedure is performed, allows evaluation of safety of the entire spectrum of procedures reportable by the unlisted code. By considering the entire range of possible procedures for the particular anatomic location against the safety criteria to be satisfied, one can determine whether there is reason to exclude the unlisted code in question. Asking whether or not any procedure performed on the anatomic structure(s) in question would 1) involve major blood vessels, 2) require major or prolonged invasion of body cavities, 3) result in extensive blood loss, 4) be emergent or life-threatening in nature, 5) require systemic thrombolytic therapy, 6) be included on the inpatient list or 7) require an overnight stay allows a logical and comprehensive assessment of safety risk based on the criteria that CMS has established.

The Ocular Adnexa section of CPT provides a useful example of how such an appraisal could be performed. The unlisted procedure code for this particular section is 67399, *Unlisted procedure, ocular muscle*. It is possible, based on clinical knowledge of all the possible procedures performed on the ocular muscles, to evaluate the full spectrum of those possibilities against safety criteria

[2] 72 Fed Reg. 50469, 50471-72 (Aug. 31, 2007).

CMS uses to determine whether a procedure should be excluded from ASC payment due to safety concerns. In this particular example, the questions asked would be as follows:

1) Does any procedure performed on the ocular muscles involve major blood vessels?
2) Does any procedure performed on the ocular muscles require major or prolonged invasion of body cavities?
3) Does any procedure performed on the ocular muscles result in extensive blood loss?
4) Is any procedure performed on the ocular muscles emergent or life threatening in nature?
5) Does any procedure performed on the ocular muscles involve systemic thrombolytic therapy?
6) Are any of the procedures performed on the ocular muscles on the inpatient list?
7) Would any procedure performed on the ocular muscles require an overnight stay?

Based on clinical knowledge of the ocular muscles and an understanding of the operative techniques and approaches to the ocular muscles, it is possible to answer all the questions above for any procedure that might be appropriately coded as CPT 67399. In this case the answer to all questions would be no. Therefore, no procedure on the ocular muscles would pose a safety concern. Given this, CMS should not exclude CPT 67399 from ASC payment.

Other unlisted surgical CPT codes should be evaluated with this same series of questions. For example, an assessment of 67299, *Unlisted procedure, posterior segment of the eye* should ask whether any procedure performed on the vitreous, retina, or choroid of the eye would involve major blood vessels, require major or prolonged invasion of body cavities, result in extensive blood loss, be emergent or life-threatening in nature, require systemic thrombolytic therapy, be included on the inpatient list or require an overnight stay. Because none of these criteria are concerns for the entire extent of procedures performed on the posterior segment of the eye, there is no reason to exclude an unlisted procedure on the posterior segment of the eye based on established safety criteria. CPT code 67299 should therefore be payable in the ASC setting.

On the other hand, a similar evaluation of CPT code 33999, *Unlisted procedure, cardiac surgery*, based on knowledge of the potential universe of cardiac procedures, would highlight multiple safety concerns. When considering cardiac surgeries, the evaluator would determine that these operations involve major blood vessels, may require major or prolonged invasion of body cavities, may result in extensive blood loss, and may be emergent or life-threatening in nature, and so on. Therefore, based on current criteria, CPT code 33999 would be appropriately excluded from ASC payment.

CMS should be consistent and evaluate unlisted codes for potential safety risks in both the ASC setting and the HOPD setting. The approach outlined above could be modified for HOPDs by incorporating the specific criteria that CMS uses to determine which procedures should be on the inpatient list under the hospital OPPS. This approach would allow CMS to assure beneficiary safety without being unduly restrictive.

C. Payment Bundles

The final rule made significant strides toward better aligning the payment bundle for ASCs and HOPDs. Allowing ASCs to bill separately for ancillary services integral to the primary procedure and separately

payable under the OPPS is a significant improvement to the alignment of the payment systems. We remain concerned, however, that discounting the payment to ASCs for many of these ancillary services does not recognize that the difference in costs for these services does not vary significantly between the ASC and HOPD.

In principle, we agree that services that are "packaged" under OPPS, and therefore not separately payable to HOPDs, should not be eligible for payment of a separate ASC facility fee. However, the proposed changes to the OPPS packaging policies will exacerbate problems that arise directly from limiting payment for surgical procedures performed in ASCs to those that fall in the range of CPT codes 10000-69999. While we agree with much of the agency's underlying logic to expand the size of the payment bundle in the OPPS, the practical application of the revised bundles in the ASC payment system create several concerns discussed in detail below.

In the agency's expanded packaging policies, even more procedures safely performed in an ASC will be packaged with services outside the CPT surgical range (CPT 1000-69999). Several of the procedures proposed for packaging have been, or could be safely performed in an ASC. Under the proposed policy change, these procedures would no longer be available in the ASC. When this happens, a procedure that had been (or would otherwise be) eligible for payment in the ASC becomes newly ineligible because of a change in OPPS packaging policy couples that CPT code with a service outside the surgical CPT range—not because there has been a determination that the procedure is unsafe in the ASC. We strongly urge the agency not to exclude radiologic services that include procedures in the CPT surgical range that would otherwise be eligible for ASC payment. If the agency does not adopt this policy prospectively, we ask that CMS at least adopt such a policy for procedures on the ASC list in 2007.

Specifically, the current OPPS policy creates barriers for ASCs to continue performing selected services that meet CMS's definition of ASC surgical services (CPTs 10000-69999). Procedures such as diskography have both an injection component and a radiographic component. In CPT, the injection portion of the service is described by a code in the surgical range (in this example, 62290 or 62291), while the radiographic portion of the service is described by a code in the radiology range (in this example, 72285 and 72295). Under OPPS, the injection portion of the procedure is packaged into the radiographic portion of the procedure. As a result, only CPT codes 72285 and 72295 are payable in the HOPD.

In our comments regarding the August 2006 proposed rule, we noted that ASCs may not be able to offer these services to Medicare beneficiaries unless they had the opportunity to bill for the combined service under the associated radiology code. Although CMS has adopted policies that will allow ASCs to bill for selected radiology services as ancillary services when provided integral to the surgical service under the revised ASC payment system, the codes for radiology services that package a surgical service have not been designated as separately payable. CMS has stated that it sees no rationale for offering separate payment for the surgical portion of these services. However, the surgical service is a necessary precedent to the radiologic service in these cases and the radiologic service cannot be properly performed in absence of the surgical injection procedure.

In this proposed rule, CMS has outlined expanded OPPS packaging policies that would further affect the payment of these services. As proposed, the radiologic services in question would be packaged into the APC payment for other associated independent services, and would no longer be separately payable when performed with other services under OPPS. CMS has recognized that these imaging guidance and

radiologic supervision and interpretation services are occasionally performed independently. Accordingly, a new status indicator, "Q," has been devised that would allow OPPS payment when these radiologic services are the only ones reported on the claim.

ASCs should also have the opportunity to receive separate reimbursement for these services when they are the only service reported on the claim. Applying this policy to both payment systems acknowledges that a surgical service has in fact been performed and allows payment for services rendered. We propose CMS implement status indicator "Q" (or an equivalent) to allow separate ASC payment of services similarly designated under OPPS, if performed in isolation.

Under the revised payment system all radiological services will be treated as ancillary services. Therefore, if the radiologic service code was or is the only one billed on the ASC claim, no "primary" surgical service would be noted on the claim because the surgical service is packaged with the radiology service. In light of this, it may be necessary to create a special payment modifier to facilitate the processing of the ASC claim. This modifier could be appended to the radiologic service code to indicate that a surgical service has also been rendered in addition to the radiologic service. CMS could require reporting of the surgical service code as a means of ensuring the ASC certifies both components of the service have been rendered.

If CMS does not elect to adopt this proposal, we request that the agency outline an alternative approach for ASC providers who wish to offer these surgical services to Medicare beneficiaries. As we have pointed out in the past, one of the predominant trends in today's clinical practice is the integration of multiple disciplines and modalities to streamline patient care. These integrated care processes enhance efficiency and quality. However, payment policies that view these services in separates silos can disrupt these interrelationships and limit beneficiary access to efficiently integrated services, particularly in the ASC setting.

Table 1 presents those surgical service codes in the CPT Surgery section that are impacted by the newly proposed OPPS packaging policies. The corresponding radiologic service codes are all proposed for assignment to status indicator "Q." Given potential changes with the upcoming 2008 CPT revisions, these codes should not be viewed as definitive, but rather as examples under the current version of CPT.

Of particular interest in this table are CPT codes 19290 and 19291, which have been covered ASC services for many years and have been paid by CMS as separately identifiable services. These services have been packaged into CPT codes 77031 and 77032 under OPPS. Under the newly proposed policies, CMS has not assigned a status indicator "Q" to CPTs 77031 or 77032, but rather a status indicator "N". We believe this is an error, as these services are occasionally performed as the sole service, and wish to draw the agency's attention to the need for correction.

Table 1
Surgical Services Packaged into SI "Q" Radiologic Services under OPPS

Surgical Code(s)	Corresponding CPT Code(s) for Radiologic Service	Descriptor of Payable Radiologic Service Code
68850	70170	X-ray exam of tear duct
21116	70332	X-ray exam of jaw joint
31708	70373	Contrast x-ray of larynx

42550	70390	X-ray exam of salivary duct
31708, 31710, 31715	71040-60	Contrast x-ray of bronchi
62284	72240-70	Contrast x-ray of spine
62291	72285	Diskography, cervical or thoracic
62290	72295	Diskography, lumbar
23350	73040	Contrast x-ray of shoulder
24220	73085	Contrast x-ray of elbow
25246	73115	Contrast x-ray of wrist
27093, 27095	73525	Contrast x-ray of hip
27370	73580	Contrast x-ray of knee joint
27648	73615	Contrast x-ray of ankle
49400	74190	X-ray exam of peritoneum
47505	74305	X-ray bile ducts/pancreas
47500	74320	Contrast x-ray of bile ducts
50394, 50684, 50690	74425	Contrast x-ray, urinary tract
51600, 51605	74430	Contrast x-ray, bladder
55300	74440	X-ray, male genital tract
54230	74445	X-ray exam of penis
51610	74450	X-ray, urethra/bladder
51600	74455	X-ray, urethra/bladder
58340	74740	Hysterosalpingography
38790	75801-07	Lymph vessel x-ray
49427	75809	Nonvascular shunt, x-ray
38200	75810	Vein x-ray, spleen/liver
36481	75885-87	Vein x-ray, liver
20501, 49424	76080	X-ray exam of fistula
19290, 19291	77031	Stereotactic guidance breast biopsy or needle
19290, 19291	77032	Mammographic guidance, placement breast needle
19030	77053, 77054	X-ray of mammary duct

D. Device-Intensive Services

We appreciate the agency's recognition that application of the discount of approximately 35% to the device portion of certain procedures would result in an ASC facility fee that fails to cover the cost of the device and the surgical service. We urge the agency to monitor the migration of procedures involving devices from hospital outpatient departments during the four transition years and consider accelerating the transition period for these procedures if warranted. The Coalition has concerns about the effect of the transition on two specific categories of procedures involving devices.

There are a number of procedures currently performed in ASCs which receive separate and additional payment for implantable devices and which have not been designated by CMS as device intensive procedures in the new payment system. During the first years of the transition, as the rates are phased in, the payment for these types of procedures may not adequately cover the costs for the procedure and the cost of the implants. CMS may also want to consider reducing the threshold for identifying procedures to be paid as device-intensive if services that could migrate to the ASC setting remain in the hospital outpatient department. In these cases, the cost of the device may be less than 50 percent of the APC rate, but more than what the ASC can afford under the discounted conversion factor.

One example of this type of procedure is CPT 66180, commonly known as a glaucoma drainage implant (Baerveldt, Molteno, Ahmed shunts), which was performed 40 percent of the time (almost 2750 times) in ASCs setting in 2005. For the sickest glaucoma patients facing irreversible vision damage, the standard

trabeculectomy procedure performed to move fluid out of the eye and relieve pressure may not be an option, or may have been tried and failed. For these patients, inserting a shunt to relieve intraocular pressure is necessary. For some of these high-risk patients there may be other medical indications, such as anatomic anomalies or scarring, for shunt placement. Under the new ASC payment system, the shunt used in these cases will no longer be separately payable. However, CMS has not included CPT 66180 on the list of device-intensive procedures. The total expected payment in the ASC for code 66180 in 2008 is only $940.81. On average, the typical shunt device costs approximately $650 and the pericardial graft tissue used to cover the tube shunt is an additional $255, for a total device cost of $905. Previously, the ASC facility payment for this service was $717, plus additional payment for the devices of about $964, for a total of $1681, which typically covered the facility's costs. The total expected payment in the ASC for code 66180 in 2008 is only $940.81.

A second example is CPT 57288, repair bladder defect, which is included in a device-dependent APC (202) under OPPS, but not classified as device-intensive under the revised ASC payment system. The proposed payment for the first year of the transition is $985.14. The cost of the sling alone is $1095.00, which exceeds the proposed reimbursement (Johnson & Johnson, Gynecare TVT Secur®).

Another example of this category of procedure is CPT 51715, endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck. As with the previous example, this is a procedure for which an implantable product, injectable bulking agent, is currently paid separately, but will not be under the new payment system. The ability of ASCs to perform this procedure during the early years of the transition period should be closely monitored by CMS.

Another category of procedure that should be monitored by CMS during the transition period is one that has been added to the ASC list in the recent past, but has been virtually never performed since its addition because of an inadequate payment associated with it. A procedure in this category is CPT 55873, prostate cryosurgery. This procedure was added to the list of ASC procedures in July 2005 and, because of the associated device costs, has rarely been performed in ASCs for Medicare beneficiaries due to the cost of the device, for which ASCs have been unsuccessful in receiving separate payment. In 2005, according to physician claims, this procedure was performed 11 times in an ASC and in 2006 only once. A transition payment policy for a procedure that is virtually never performed because of inadequate payment does not make sense. Such procedures may need to be treated in the same manner as procedures added to the ASC list in 2008 and subsequent years. Again, CMS should closely monitor these types of procedures and adjust payment policies if appropriate.

If one major purpose of the new ASC payment system is to encourage the migration of procedures from HOPD to ASCs, it will be imperative for CMS to closely monitor the effect of the four year transition on ASC procedures for which separate payment for implants is currently made and for procedures that are virtually never performed because the rate is insufficient to cover the included implant. The Coalition suspects that the speed with which these types of procedures migrate could be significantly retarded if payment levels during the early years of the transition are inadequate. As a result, these services will continue to be provided primarily in the more expensive hospital setting. The Coalition believes that the number of procedures that fall into these categories is small and that any adjustment in the payment policies for them would not adversely affect average rates for other procedures even in the context of maintaining budget neutrality.

E. Payment Limits

Although we applaud CMS's expansion of the ASC procedure list, we continue to oppose CMS's payment cap on office-based procedures. CMS has decided that those procedures it determines are commonly performed in physicians' offices or are otherwise determined to be office-based, shall be paid the lesser of the applicable ASC rate or the applicable Medicare physician fee schedule (MPFS) rate. The unfairness of this policy is underscored by the fact that the "lesser of" rule is not applied to payment to hospital outpatient departments. CMS has not demonstrated that procedures commonly performed in physicians' offices are more likely to migrate to an ASC than a hospital outpatient department. Therefore, this "lesser of" rule should either be abandoned completely or applied to payment to ASCs as well as hospital outpatient services. CMS appears to be using payment rates to address the agency's concerns about provider's financial interests rather than the clinical needs of patients.

The payment limit will force patients who are not appropriately treated in the physician office or who go to a physician who does not have appropriate equipment or staff in their office for the procedure to go to an HOPD, bypassing the ASC where the service could safely and cost-effectively be performed. Physician offices generally treat a less complex and severely ill patient case mix. As such, the office is less likely to have the staff and equipment resources to provide on a regular basis many of the services that a more medically complex patient might require. Capping payment at the physician office rate undermines the stepped reimbursement policies that underlie the level of resources available to the physician and beneficiary at the ASC and physician office.

Although we disagree with CMS's assertion that significant volume of these procedures will move from the physician office into the ASC, we recognize that the agency wants to discourage migration of services into a more expensive setting. However, in previous cases where CMS has made exceptions to allow ASC payment for procedures primarily performed in the office, there have not been significant shifts in the site of service for those procedures.[3]

These findings are in accord with findings we have made, which are that physicians typically do not bring procedures to the ASC when those procedures can be appropriately performed in their offices. Physicians seek to provide services in the most convenient setting that is appropriate. Physicians who have acquired the equipment and personnel to perform these procedures will want to continue to provide such services in their office. Unfortunately, capping payments for these procedures will primarily hurt the beneficiary and ultimately raise costs for the beneficiary and the Medicare program. Further, we are concerned with the agency's process for identifying and permanently designating procedures as "office-based" services.

CMS should not limit payment for services that draw on costly facility resources for patients for whom the physician office is not the clinically appropriate site of service. First, using 50 percent as the threshold for identifying office-based procedures means that for some services, they are just as frequently performed in another outpatient setting like the ASC or HOPD. That said, there must be a clinical need for facility-level resources since the remaining half of the Medicare beneficiaries receiving the service are treated in the ASC or HOPD. Failing to provide adequate payment to ASCs to perform the procedures may lead to higher volume in the HOPD rather than contributing to the migration of ASC volume into the physician

[3] 70 Fed. Reg., 23696 (May 4, 2005). CMS stated, "Consistently, the physician office is the predominate service setting even though the procedures were included on the ASC list."

office. CMS should set the threshold for designating a service at office-based significantly higher so that the designation applies only to services where facility-level care is infrequently warranted.

We are also concerned by CMS' plan to permanently designate a service as office-based using only one year of volume data. Especially for low-volume procedures, the distribution of services between settings can vary substantially from year-to-year. An office-based designation set at the 50 percent threshold should not be a permanent designation. If this policy remains, CMS should, at a minimum, use multiple years of data to assess whether the procedure is consistently performed in the office setting. For procedures with low volume in which a small number of services can make a large difference, or those whose percentage hovers close to the threshold, we believe a multi-year average is a more appropriate measure of whether a service has truly migrated into the physician office.

Finally, we are very concerned that CMS will use unidentified data as a secondary mechanism to designate "office-based services." As discussed in both the proposed and final rule, when CMS is designating codes as office based, it is not solely identifying procedures based on the latest volume data but evaluating clinical information and comparable data for related procedures "as appropriate." Without identifying the data CMS will use to make a determination that a procedure is office-based, it will be impossible to assess whether such a determination is rational and fair. We urge CMS to adopt a more transparent mechanism to designate office based procedures.

In the final rule implementing ASC payment system reform, CMS designated almost 70 procedures as "office-based services" that also do not meet the "predominantly performed" volume threshold. (Appendix B). In this proposed rule, CMS is proposing an additional 12 procedures to be designated as office-based which do not meet the "predominantly performed" volume threshold. (Appendix A). Physicians are already performing many of the "office-based" procedures in the ASC setting on patients that may require the additional services available in the ASC, rather than taking these procedures to the more expensive hospital setting.

The policy limiting payment for procedures designated as "office-based services" should be eliminated unless it is equally applied to the hospital outpatient department. Site of service volume characteristics are arbitrary and without clinical basis and should not be used to determine ASC payment. However, should CMS choose to do so, services should not be designated "office-based services" indefinitely but should be evaluated solely based on whether or not they are infrequently performed in the HOPD or ASC. The 50 percent threshold is too low and should higher. Further, CMS should not use clinical information or comparable data *for related procedures* to determine what should be office-based. If CMS continues to use other data, it should provide the data and rationale employed in making that determination.

F. Inflation Update

CMS should utilize the same market basket annual inflation to determine the annual update for ASCs. ASCs are affected by the same inflationary costs as hospitals, such as hiring nurses and purchasing medical devices, which are unrelated to general consumer price increases. CMS has presented no evidence that the relative costliness of procedures in the ASC and HOPD diverge over time. The broad discretionary authority granted to the Secretary to implement the new payment system should be used to apply the hospital market basket to the ASC payment system. Absent that adjustment, this bifurcated update process will result in annual, larger variation between the rates paid for ASC and hospital outpatient services.

G. Secondary Rescaling of APC Relative Weights

CMS applies a budget neutrality adjustment to the OPPS relative weight values after they are recalibrated with new cost data each year and decided to apply a secondary rescaling of the ASC weights. As expected, the relative costliness of surgical services continues to outpace the cost growth of non-surgical services in the OPPS. Applying a secondary recalibration to the ASC, absent evidence that ASC services became relatively less expensive than the HOPD, will drive unjustified variation in the payment rates between the ASC and HOPD. We question whether policies that lead to government paying increasingly higher rates under the OPPS is appropriate and justifiable given that many patients could have safely received their procedure in an ASC if one were available.

H. Application of HOPD Policies to the ASC

We appreciate CMS using their authority to extend several HOPD policies to the new ASC payment system. Although few items are eligible for pass-through status each year, accelerating the diffusion of new technologies to ambulatory settings is an important policy objective for the payment systems. As CMS considers future policies in the OPPS, we urge the agency to apply the same policies to the ASC.

We note that the agency used their authority under 1833(t)(2)E) to adjust payment under the OPPS for several gastroenterology procedures that would have otherwise been paid the lower ASC discounted rate under a policy enacted in the Balanced Budget Act of 1997. Specifically, CMS stated that the payment for screening flexible sigmoidoscopies and screening colonoscopies would be too low if CMS followed the statute and paid for the services at the lesser of the ASC or OPPS rates. Instead, the agency will pay for the services at the standard OPPS rate. On the other hand, CMS has not taken similar steps to ensure that that beneficiary access to services in the ASC will not be negatively affected. Because the preventative screening benefit is currently under-utilized, we urge the agency to carefully monitor the utilization of the benefit and make adjustments as necessary.

I. Billing Systems

In the final rule, CMS decided to continue to require the use of the CMS 1500 form for providers to submit claims for their services. As CMS and providers gain experience with the new payment system, we urge the agency to complete the alignment of the payment system by migrating to the UB-04 for ASC claims submission. Many commercial payers require ASCs to submit claims using the UB-04. CMS should initiate a transition process for providers and the agency's administrative contractors to implement the UB-04 form for ASCs in 2010 to allow providers time to acclimate to the new payment system in 2008 and the reporting of quality measures in 2009.

K. Beneficiary Liability for Non-Covered Services.

Current OPPS payment policy prohibits facility payments to a hospital for non-covered services, such as surgical procedures on the OPPS inpatient list. In those cases, the beneficiary is liable for the hospital charges. CMS has proposed to implement a similar policy for non-covered ASC services. This policy assumes that all non-covered procedures are scheduled as such and does not acknowledge the possibility that a covered procedure was planned, but not performed for legitimate reasons that could not be anticipated in advance, resulting in a non-covered procedure being performed instead.

Though not typical, it is possible for intraoperative findings to alter the course of a planned procedure. When these unpredictable events occur, it is not reasonable to burden the beneficiary with full financial

liability for the non-covered procedure. Acknowledging that the course of a planned procedure cannot always be determined in advance and allowing for contractor-based adjudication allows for more equitable treatment of beneficiaries under these circumstances. Under such circumstances, standard cost-sharing formulas should remain in effect. A modifier could be created that allows communication of these circumstances on both ASC and HOPD claims. In these cases, payment would be at contractor-priced rates following a review of the operative report. Any concerns regarding billing practices could be readily audited, since scheduling a procedure creates a record of the planned intervention. We urge CMS to alter its current policy under OPPS and apply this modified policy to the ASC and HOPD setting.

L. Reporting Quality Data for Annual Payment Rate Updates as it pertains to ASCs

We commend CMS for deciding not to implement ASC reporting of quality measures prior to January 1, 2009. With the implementation of the revised ASC payment system in 2008, the ASC community will have a significant transition and we are pleased additional requirements will not be introduced simultaneously. The current absence of any nationally endorsed ASC quality measures for public reporting and accountability would have been a further barrier to implementation in 2008. However, we anticipate ASC quality measures will be endorsed by the National Quality Forum (NQF) by the end of 2007 and available for implementation in 2009. The ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring that ASC quality data is appropriately developed and reported, is developing standardized ASC quality measures. Its members include ASC companies, associations, physician societies, accrediting bodies and government entities.

Quality Measures. The ASC Quality Collaboration has submitted a series of measures to the NQF, which have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement and have recently been open to public and NQF member comment. We anticipate that final action on these measures could be taken as early as November 2007. We are not aware of any other measures specifically addressing facility quality in the delivery of outpatient surgical services that have either been nationally endorsed or are in the process of evaluation for endorsement. Therefore, we strongly recommend CMS consider these five facility-specific measures for ASC reporting if they are endorsed by the NQF.

Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure that evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (PQRI #20 and PQRI #21) developed to evaluate physician performance in this area.

ASC Data Collection. Our evaluation of alternative reporting methodologies has focused on their complexity, staff resources needed for implementation, requirements for hardware and software, training requirements, and additional expenses, particularly related to contracting with data submission vendors. In all these areas, we find the administrative claims approach to be the most practical, feasible and economical solution for ASCs. We have carefully evaluated these alternative approaches, taking into account the characteristics and resources of the typical ASC.

Though there is significant variability, CMS data indicates a median of two operating/procedures rooms per facility (mean = 2.5). FASA's 2007 ASC Salary & Benefits Survey shows that the majority (61.2%) of ASCs have 20 or fewer total full-time equivalents, including both clinical and non-clinical staff. It is unusual for an ASC to have a medical records department staffed with multiple individuals.

The administrative and financial burden of reporting quality measures should be fully considered. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72 Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

Further, ASCs will continue submitting their Medicare claims using the CMS-1500 at least through 2008. Therefore, ASCs are in a position to report quality data in the same manner as physicians, which will allow CMS to leverage the processes it has already developed under the Physician's Quality Reporting Initiative (PQRI). If ASCs move to the UB-04 in the future (a change we support), these codes can continue to be reported on the new form and comparisons made across multiple years remains feasible.

We request CMS work with ASC leaders to develop HCPCS Level II G codes that would allow facility-level quality measures to be reported using a claims-based approach. Reporting data on the claim form using HCPCS codes is achievable across ambulatory settings and can be accommodated on both the CMS-1500 and the UB-04.

Publication of Quality Data Collected. The demand for more publicly available health care information is being driven by federal and some state actions and by employers in an effort to control escalating health insurance costs and improve quality. The ASC Coalition is supportive of transparency oriented efforts motivated by a desire to provide consumers with information they can use in a meaningful way to improve their health and lower the cost of their care. Access to cost and quality information will become even more important to consumers as the health insurance industry moves to more consumer driven health care through Health Savings Accounts (HSAs), Health Reimbursement Accounts (HRAs) and Flexible Spending Accounts (FSAs).

The ASC Coalition urges CMS to ensure that any transparency regarding ASC cost and quality information is meaningful and presented in a way that assists consumers in making decisions. The success of transparency efforts is closely linked to how effectively information is shared with the public. A data reporting infrastructure should allow patients and payers to compare quality across Medicare's payment silos when a service or procedure can be delivered in multiple ambulatory settings.

Consumers should be able to access quality and cost information on websites that are organized to allow easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date and clearly presented. Specifically, web-based presentation of quality and cost data should address or incorporate the following principles:

1) Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations,

2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its public presentation,

3) There should be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented, and

4) In addition to reporting quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

The ASC Coalition urges CMS to provide for more detailed consideration and expanded description on this vital matter from CMS in future rulemaking.

* * * * *

We appreciate the agency's consideration of our comments on behalf of the ASC community. Inadequate payment will force providers to respond in a variety of ways – the end result of which may limit patients' ability to have their surgical service performed in a low cost environment. The implementation of the revised ASC payment system will result in significant redistribution of dollars within the ASC payment system and as such, we strongly urge CMS to use its broad discretionary authority to ensure a smooth transition to the new payment system. As leaders in the ASC industry, we want to ensure patient access is not jeopardized by abrupt changes in the payment system.

Thank you for considering our comments. If you have any questions or need additional information, we would be happy to assist you.

Sincerely,

Joseph Banno, MD
President
American Association of Ambulatory Surgery Centers

Kathy Bryant
President
FASA

Ken P. McDonald
President and Chief Executive Officer
AmSurg Corp.

David Shapiro, M.D.
Florida Society of Ambulatory Surgery Centers

Joseph T. Clark
Executive Vice President and
Chief Operating Officer
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Randy Leffler
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Ohio Association of Ambulatory Surgery Centers

Richard D. Pence
Chief Operating Officer
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Thomas Hall
President and Chief Executive Officer
NovaMed, Inc.

Richard Francis
Chairman and Chief Executive Officer
Symbion, Inc.

William H. Wilcox
President & Chief Executive Officer
United Surgical Partners International

APPENDIX A

PROCEDURES PROPOSED FOR DESIGNATION AS OFFICE-BASED BUT PERFORMED LESS THAN 50% OF TIME IN THE PHYSICIAN OFFICE IN 2006

HCPCS	SHORT DESCRIPTION	FINAL RULE INDICATOR	PROPOSED RULE INDICATOR	CY 2006 OPPS UNITS	CY 2006 MPFS IN OFFICE ALLOWED SERVICES	TOTAL VOLUME	% MD OFFICE
24640	Treat elbow dislocation	G2	P3	51	18	69	26.09%
26641	Treat thumb dislocation	G2	P2	66	29	95	30.53%
26670	Treat hand dislocation	G2	P2	72	29	101	28.71%
26700	Treat knuckle dislocation	G2	P2	522	106	628	16.88%
26775	Treat finger dislocation	G2	P3	264	217	481	45.11%
28630	Treat toe dislocation	G2	P3	100	95	195	48.72%
28660	Treat toe dislocation	G2	P2	295	159	454	35.02%
29505	Application, long leg splint	G2	P3	19482	1106	20588	5.37%
29515	Application lower leg splint	G2	P3	56482	17910	74392	24.08%
36469	Injection(s), spider veins	G2	R2	3	1	4	25.00%
46505	Chemodenervation anal musc	G2	P3	163	37	200	18.50%
64447	Nblock inj fem, single	G2	R2	1381	950	2331	40.76%

APPENDIX B

PROCEDURES PERFORMED LESS THAN 50% OF TIME IN PHYSICIAN OFFICES WHEN DESIGNATED AS OFFICE-BASED IN THE FINAL RULE

CPT	SHORT DESCRIPTION	CY 2005 OPPS UNITS	CY 2005 MPFS IN OFFICE ALLOWED SERVICES	TOTAL VOLUME	% MD
0046T	Cath lavage, mammary duct(s)	3	1	4	25.00%
0047T	Cath lavage, mammary duct(s)	0	0	0	--
11950	Therapy for contour defects	39	32	71	45.07%
11951	Therapy for contour defects	43	10	53	18.87%
11952	Therapy for contour defects	19	6	25	24.00%
11954	Therapy for contour defects	196	34	230	14.78%
11976	Removal of contraceptive cap	31	11	42	26.19%
12001	Repair superficial wound(s)	132984	36471	169455	21.52%
12002	Repair superficial wound(s)	98727	23901	122628	19.49%
12004	Repair superficial wound(s)	14338	2748	17086	16.08%
12011	Repair superficial wound(s)	70950	9485	80435	11.79%
12013	Repair superficial wound(s)	39628	4734	44362	10.67%
12014	Repair superficial wound(s)	5222	548	5770	9.50%
15340	Apply cult skin substitute	15359	6617	21976	30.11%
15783	Abrasion treatment of skin	86	25	111	22.52%
15786	Abrasion, lesion, single	472	373	845	44.14%
15787	Abrasion, lesions, add-on	155	54	209	25.84%
26010	Drainage of finger abscess	1975	1790	3765	47.54%
29010	Application of body cast	3	2	5	40.00%
29049	Application of figure eight	22	14	36	38.89%
29055	Application of shoulder cast	27	21	48	43.75%
29058	Application of shoulder cast	118	43	161	26.71%
29086	Apply finger cast	580	228	808	28.22%
29105	Apply long arm splint	18280	9569	27849	34.36%
29125	Apply forearm splint	120178	32832	153010	21.46%
29126	Apply forearm splint	6623	702	7325	9.58%
29130	Application of finger splint	26636	8515	35151	24.22%
29131	Application of finger splint	1534	459	1993	23.03%
29240	Strapping of shoulder	17263	6576	23839	27.59%
29260	Strapping of elbow or wrist	6187	5690	11877	47.91%
29358	Apply long leg cast brace	146	91	237	38.40%
29530	Strapping of knee	18662	13284	31946	41.58%
29700	Removal/revision of cast	3525	2380	5905	40.30%

CPT	SHORT DESCRIPTION	CY 2005 OPPS UNITS	CY 2005 MPFS IN OFFICE ALLOWED SERVICES	TOTAL VOLUME	% MD
29710	Removal/revision of cast	17	4	21	19.05%
29715	Removal/revision of cast	12	2	14	14.29%
30901	Control of nosebleed	67943	60188	128131	46.97%
36430	Blood transfusion service	477254	15877	493131	3.22%
36440	Bl push transfuse, 2 yr or <	24	7	31	22.58%
36450	Bl exchange/transfuse, nb	59	30	89	33.71%
36468	Injection(s), spider veins	68	42	110	38.18%
36550	Declot vascular device	12215	11617	23832	48.75%
36598	Inj w/fluor, eval cv device	6388	3343	9731	34.35%
38242	Lymphocyte infuse transplant	37	8	45	17.78%
41820	Excision, gum, each quadrant	376	1	377	0.27%
41822	Excision of gum lesion	27	14	41	34.15%
41823	Excision of gum lesion	95	41	136	30.15%
41830	Removal of gum tissue	218	107	325	32.92%
41850	Treatment of gum lesion	26	4	30	13.33%
41872	Repair gum	422	0	422	0.00%
41874	Repair tooth socket	4473	573	5046	11.36%
46606	Anoscopy and biopsy	876	619	1495	41.40%
46910	Destruction, anal lesion(s)	531	340	871	39.04%
46945	Ligation of hemorrhoids	1108	1068	2176	49.08%
51702	Insert temp bladder cath	1211839	145409	1357248	10.71%
53025	Incision of urethra	0	0	0	--
55450	Ligation of sperm duct	8	5	13	38.46%
55870	Electroejaculation	16	4	20	20.00%
55876	Place rt device/marker, pros	1293	245	1538	15.93%
58345	Reopen fallopian tube	5	3	8	37.50%
58356	Endometrial cryoablation	21	16	37	43.24%
59001	Amniocentesis, therapeutic	8	4	12	33.33%
59015	Chorion biopsy	18	9	27	33.33%
59020	Fetal contract stress test	357	9	366	2.46%
59025	Fetal non-stress test	11562	5260	16822	31.27%
60100	Biopsy of thyroid	12967	7236	20203	35.82%
63615	Remove lesion of spinal cord	4	2	6	33.33%
64402	Nblock inj, facial	1312	874	2186	39.98%
67208	Treatment of retinal lesion	454	374	828	45.17%

APPENDIX C

OTHER PROCEDURES FOR ADDITION TO THE ASC LIST FOR 2008

CPT	DESCRIPTION	COMMENTS
22526 22527	Percutaneous intradiscal electrothermal annuloplasty (IDET or IDEA)	These are minimally invasive surgical procedures for the treatment of discogenic lumbar pain. These procedures are commonly performed in the outpatient setting, with discharge on the day of the procedure. Following placement of a local anesthetic and administration of sedation, an introducer is placed through a small incision and fluoroscopically guided to the affected lumbar disc. An electrothermal catheter is passed through the introducer and positioned in the annulus. Electrothermal energy is applied via the catheter for a period of 15 to 20 minutes. These procedures are clinically similar to 0062T/0063T, which are included in Addendum AA for ASC coverage.
29866 29867 29868	Knee arthroscopy with autograft implantation or meniscal transplantation	These knee arthroscopy procedures were added as CPT codes in 2005 and are clinically similar to the 29800-29888 series of codes, which are on the ASC list. They typically require approximately 45 minutes of operating time and do not require an overnight stay.
35470	Transluminal balloon angioplasty	This procedure is safe to perform in the ASC and does not require an overnight stay. It involves peripheral vessels, takes approximately one hour and does not require overnight recovery. It is similar to, but less invasive than, 37205 and 37206, which CMS added to the ASC list in 2005.
35493	Transluminal peripheral artherectomy	This procedure involves peripheral vessels and is safe to perform in an outpatient setting. The procedure typically takes approximately one hour to complete and does not require an overnight stay.
63030 63035 63042 63047	Low back disk surgery	While Medicare patients primarily have lower back disc surgery performed on an inpatient basis, a growing number of non-Medicare patients (and some Medicare patients who choose to pay out of pocket) are having these procedures performed in ASCs, often using endoscopically-assisted approaches. The procedures are non-emergent, do not involve a major or prolonged invasion of a body cavity and do not involve major blood loss. In ASC settings, these procedures involve 60 to 90 minutes of operating room time and do not require an overnight stay.
64448 64449	Injection of anesthetic agent (nerve block) for femoral nerve or lumbar	These procedures are already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make these procedures available to Medicare

CPT	DESCRIPTION	COMMENTS
	plexus, with continuous infusion by catheter	beneficiaries as they often are performed in conjunction with other pain management procedures. By denying Medicare coverage for these procedures, CMS creates an obstacle to their efficient performance with other procedures in ASCs.
0088T	Submucosal radiofrequency volume reduction of the tongue base, or somnoplasty	This is a commonly performed outpatient procedure for the treatment of obstructive sleep apnea or upper airway resistance syndrome. The radiofrequency probe is inserted into the tongue muscle and then heated, producing tissue injury that, after healing, reduces the volume of the tongue. Patients typically receive local anesthesia. Procedure time is less than 45 minutes and patients are discharged home on the day of the procedure. The procedure is clinically similar to, though less invasive than, excisional procedures involving the tongue described by CPTs 41110 and 41113, both of which will be covered in the ASC setting.
0135T	Percutaneous cryosurgery of renal tumors	This procedure is a minimally invasive treatment option for patients with small cortical renal tumors. The procedure requires general or regional anesthesia. Ultrasound or other guidance modalities are used to guide placement of the cryoablation needles and thermal sensors. Following completion of two freeze thaw cycles, the patient is monitored in recovery and discharged on the day of the procedure. This procedure is clinically similar to CPT 50592, Percutaneous radiofrequency ablation of renal tumor(s), which is included in Addendum AA for coverage in the ASC setting.
0137T	Prostate saturation biopsy	Prostate saturation biopsy is typically performed in an outpatient setting using intravenous sedation. This procedure involves taking a greater number of prostate biopsies than have traditionally been taken during one procedure. The patient is discharged on the same day. This procedure is clinically similar to CPTs 55700 and 55705 describing prostate biopsy, which are currently covered in the ASC setting.
0170T	Anal fistula repair with a biodegradable porcine small intestinal mucosal plug	This procedure is an outpatient surgical procedure that can be performed under general, spinal or local anesthesia. Following identification of the internal and external fistula tract openings, the plug is pulled into the tract using suture ligatures and subsequently sutured in place. Patients are discharged home on the day of the procedure. The procedure is clinically similar to CPT 46706, Repair of anal fistula with fibrin glue, which currently on the ASC list of covered procedures.

CPT	DESCRIPTION	COMMENTS
0184T	Transanal endoscopic resection of a rectal tumor	This Category III CPT code will be implemented on January 1, 2008. Transanal endoscopic microsurgery is a minimally invasive procedure for the excision of precancerous lesions or early cancers of the rectum. This procedure can be performed on an outpatient basis, with discharge on the same day. It is clinically similar to CPT 45170, Excision of rectal tumor, which is currently on the ASC list of covered procedures.
0186T	Suprachoroidal drug delivery	This Category III CPT code will be implemented on January 1, 2008. A microcannula is introduced into the suprachoroidal space and used as a means to deliver drugs to the macula, optic nerve and posterior pole. This in an outpatient procedure and patients are discharged on the same day. The procedure is clinically similar to CPTs 67027 and 67028 (describing intravitreal drug delivery), which are both included in Addendum AA for ASC coverage in CY 2008.

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September 14, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Room 455-G Hubert H. Humphrey Buildings
200 Independence Avenue, S.W.
Washington D.C. 20201

Re: Proposed Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-1392-P)

Dear Mr. Weems:

The American College of Radiation Oncology ("ACRO") appreciates the interest of the Centers for Medicare and Medicaid Services (CMS) in receiving comments on the Proposed Rule that addresses the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-1392-P). With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. Over 20% of the radiation oncologists in the United States are members of ACRO. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology. Our members practice in both freestanding centers and hospital outpatient departments.

ACRO would like to extend its appreciation for the opportunity to comment on the proposed regulations.[1] This letter will comment on the following sections:

- Packaging of Guidance Services and Image Processing Services;
- High Dose Electronic Brachytherapy; and
- Stereotactic Radiosurgery Services.

[1] "Proposed Rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-1392-P)" *Federal Register*, Volume 72, No. 148, August 2, 2007, p. 42627.

A. OPPS PACKAGED SERVICES: Guidance Services and Image Processing Services

ACRO would like the opportunity to review the packaging information in order to understand how the costs of the dependent CPT are assigned to independent procedures. Specifically, ACRO requests that CMS detail: (a) which dependent procedures are associated with which independent procedures; (b) the percentage of independent procedures that were associated with each assigned dependent procedure; (c) the costing of each procedure with and without the packaging methodology. CMS should make this information publically available through its web site. Only through such transparency, can specialty societies comment on how these codes are packaged and the potential impact. **We encourage CMS to delay the proposed packaging until complete information is made available and various constituencies have the opportunity to fully comment. We understand that the APC Panel has recommended a delay in packaging the image guidance procedures associated with radiation oncology. ACRO supports this APC Panel recommendation.**

ACRO would also like to make CMS aware that packaging dependent procedures is only appropriate for technologies that are established with stable use rates. ACRO is concerned that some dependent procedures are currently beginning to evolve into the standard of care as they are more readily available. Packaging technologies as they are being disseminated appears to "lock in" a given penetration rate at today's rate and may significantly underfund the technology as it spreads. This may weaken support for radiation oncology in general and/or slow the spread of new, important technologies. ACRO believes that a stable use rate would require at approximately five years to achieve. ACRO supports delaying the packaging of technologies that have not reached a stable use rate in the community.

B. OPPS NEW HCPCS AND CPT Codes: High Dose Electronic Brachytherapy

ACRO would like CMS to be aware of the need to regulate this new technology. While ACRO is in agreement with the current CMS definition of a radioactive source, there is a need to recognize that electronic brachytherapy artificially creates radioactivity. This newly created radioactive material must be closely monitored by individuals trained in handling radioactive materials and knowledgeable in public and patient safety issues. ACRO remains concerned that patient safety and good clinical outcomes require careful consideration of total dose, time dose relationships, volume of tissue treated, organs at risk and other radiobiological considerations. Electronic brachytherapy carries the same risks for patient and public safety as does traditional radionuclide brachytherapy; in addition, there are the compounding risks of heat and electrical injury to the patient. Therefore, ACRO feels strongly that the use of electronic brachytherapy, as with all radiation treatment, should be supervised, delivered and managed by physicians trained and experienced in the use of radiation therapy. **ACRO will be working closely with state regulatory agencies to educate the regulatory officials on the issues involved in electronic brachytherapy, the appropriate safeguards and training required for safe handling.**

C. SRS TREATMENT DELIVERY SERVICES

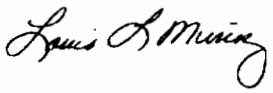
ACRO is one of the specialty societies that urge CMS to recognize CPT codes 77372 and 77373 under OPPS rather than continuing the use of Level II HCPCS codes. We believe that, while there may be differential facility resources, one technology should not be favored over another. Such a stance is in line with CMS's own belief that hospitals should be motivated to be efficient providers choosing the cost effective technology most appropriate to the treatment of the clinical condition. [2] Specifically, ACRO can find no clinical justification for the dramatic decline in reimbursement for G0251 – LINAC based stereotactic radiosurgery, over G0339 or G0340. ACRO urges the reimbursement for G0251 to be set at APC 0067.

Conclusion

ACRO's comments on the OPPS regulations seek to ensure ongoing access to radiation oncology services. In many communities, hospital outpatient units are the key providers of radiation services. Maintaining patient access is crucial since our patients often require services 5 days a week for many weeks of life saving therapy. Patient accessibility and continuity are key components of service quality.

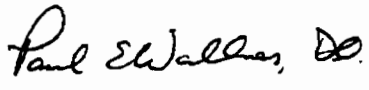
ACRO appreciates the opportunity to comment on the regulations. We hope that our comments highlight our sincere interest in making radiation oncology services cost effective, properly reimbursed and readily accessible to cancer patients.

Sincerely,



Louis Munoz, M.D., FACRO
President
American College of Radiation Oncology
5272 River Road
Suite 630
Bethesda, Maryland 20816

Sincerely,



Paul Wallner, D.O., FAOCR
Chair, Socioeconomics Committee
American College of Radiation Oncology
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Suite 630
Bethesda, Maryland 20816

CC: Herb Kuhn, Centers for Medicare and Medicaid Services
Rick Ensor, Centers for Medicare and Medicaid Services
Edith Hambrick, M.D., Centers for Medicare and Medicaid Services
Ken Marsalek, Centers for Medicare and Medicaid Services
Pam Ohrin, Centers for Medicare and Medicaid Services
Liz Richter, Centers for Medicare and Medicaid Services
Ken Simon, M.D., Centers for Medicare and Medicaid Services
Pam West, Centers for Medicare and Medicaid Services

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[2] *Federal Register*, Volume 72, No. 148, August 2, 2007, pages 42648-9 and 42651.

Congress of the United States
Washington, DC 20515

September 14, 2007

Acting Administrator Kerry Weems
Office of the Administrator
Attention: CMS-1392-P
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

RE: Separate Reimbursement Payment for Chest X-Ray Computer Aided Detection (CAD)
Issue Identifier: OPPS: Packaged Services, CMS-1392-P

Dear Acting Administrator Weems:

As members of Congress concerned about the devastating impact that lung cancer has on our nation and our constituents, we are writing to urge you to provide separate payment for chest x-ray computer-aided detection (CXR CAD) for lung cancer. It is our understanding that the Advisory Panel on Ambulatory Payment Classification Groups at its March 7-8, 2007 meeting officially recommended to your agency that it provide additional payment for CXR CAD and we fully support that recommendation. We believe that by providing separate payment for CXR CAD that the Centers for Medicare and Medicaid Services (CMS) will be taking an important step forward in the fight against lung cancer.

As you may know, each year, lung cancer takes more American lives than any other single form of cancer. In fact, the 5-year survival rate for lung cancer is only 16 percent. The most effective way to reduce the mortality rate from lung cancer is to detect lung cancer early. When lung cancer is detected early, the five year survival rate is nearly 50 percent. Fortunately, there is a new technology – CXR CAD – that helps radiologists with early detection of lung cancer. The Advisory Panel on Ambulatory Payment Classification Groups importantly recognized the value of this technology earlier this year when it recommended that "CMS place CPT 0175T, Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation, on the list of special packaged codes (SI "Q")." We understand that the current lack of a separate payment for CXR CAD is precluding a number of hospitals and communities from adopting and utilizing this vital technology. Tragically, failure to adopt this technology leaves too many Medicare beneficiaries and their physicians without access to a critical tool to catch lung cancer at its earliest and most treatable stage.

It is our understanding that in the CMS 2008 proposed Hospital Outpatient Prospective Payment System (HOPPS) rule that the Advisory Panel's recommendation was not incorporated. We are concerned that the agency did not adopt this recommendation and urge you – in the final 2008 HOPPS rule – to add CPT 0175T to the list of special packaged codes (SI "Q"). Moreover, we encourage you also to include CPT 0174T,

Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation, on the list of special packaged codes (SI "Q"). Together, additional payments for these two codes will help ensure that Medicare beneficiaries have access to the latest state-of-the-art technology for early detection of lung cancer – increasing their chances of longer-term survival should they be diagnosed with lung cancer.

By including CPT 0174T and 0175T in the list of special packaged codes beginning calendar year 2008 the agency will help ensure that CXR CAD is available to Medicare beneficiaries. We look forward to hearing back from you regarding this critical public health issue and learning from you the actions you are taking to ensure access to CXR CAD for our constituents and Medicare beneficiaries across the nation. Thank you for your attention to our concerns and requests.

Sincerely,

Dave Hobson

Marcy Kaptur

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75

United States Senate

WASHINGTON, DC 20510-3504

ENVIRONMENT AND PUBLIC WORKS
RANKING MEMBER, SUBCOMMITTEE ON CLEAN AIR, AND NUCLEAR SAFETY

FOREIGN RELATIONS

HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
RANKING MEMBER, SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE, AND THE DISTRICT OF COLUMBIA

September 13, 2007

Acting Administrator Kerry Weems
Office of the Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20001

RE: Separate Reimbursement Payment for Chest X-Ray Computer Aided Detection (CAD)
Issue Identifier: OPPS: Packaged Services, CMS-1392-P

Dear Acting Administrator Weems:

As a member of Congress concerned about the devastating impact lung cancer has on our nation and my constituents, I ask you to consider providing separate payment for chest x-ray computer-aided detection (CXR CAD) for lung cancer. It is my understanding that the Advisory Panel on Ambulatory Payment Classification Groups at its March 7-8, 2007 meeting officially recommended to your agency that it provide additional payment for CXR CAD. I believe that providing separate payment for CXR CAD may be an important step forward in the fight against lung cancer.

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Fortunately, there is a new technology – CXR CAD – that helps radiologists with early detection of lung cancer. The Advisory Panel on Ambulatory Payment Classification Groups importantly recognized the value of this technology earlier this year when it recommended that "CMS place CPT 0175T, Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation, on the list of special packaged codes (SI "Q")." I understand that the current lack of a separate payment for CXR CAD is precluding a number of hospitals and communities from adopting and utilizing this vital technology. Tragically, failure to adopt this technology may leave too many Medicare beneficiaries and their physicians without access to a critical tool to catch lung cancer at its earliest and most treatable stage.

STATE OFFICES:
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78 WEST WASHINGTON STREET
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420 MADISON AVENUE
ROOM 1210
TOLEDO, OHIO 43604
(419) 259-3895

It is my understanding that in the CMS 2008 proposed Hospital Outpatient Prospective Payment System (HOPPS) rule that the Advisory Panel's recommendation was not incorporated. I urge you – in the final 2008 HOPPS rule – to consider adding CPT 0175T to the list of special packaged codes (SI "Q").

Moreover, I encourage you also to include CPT 0174T, Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation, on the list of special packaged codes (SI "Q"). Together, additional payments for these two codes could help ensure that Medicare beneficiaries have access to the latest state-of-the-art technology for early detection of lung cancer – increasing their chances of longer-term survival should they be diagnosed with lung cancer.

By including CPT 0174T and 0175T in the list of special packaged codes beginning calendar year 2008, the agency may help ensure that CXR CAD is available to Medicare beneficiaries. I look forward to hearing back from you regarding this critical public health issue.

Sincerely,

George V. Voinovich
United States Senator

(76)

AAMC

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VIA HAND DELIVERY

September 14, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Attention: CMS–1392–P

Dear Mr. Weems:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates ..."* 72 Fed. Reg. 42627 (August 2, 2007). The AAMC represents approximately 400 major teaching hospitals and health systems; all 126 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our comments focus on the following areas: the new outpatient quality reporting program; the proposed packaging approach; the proposal to require hospitals to report pharmacy overhead charges; the proposed payment for the acquisition and handling costs of separately payable drugs and biologicals; the proposed reduction in the APC payment for procedures involving the replacement of a defective device for which the hospital receives partial credit; and evaluation and management coding guidelines. But first, we would like to address whether a teaching adjustment should be included in the outpatient prospective payment system (OPPS).

AN OPPS TEACHING ADJUSTMENT

The OPPS is the only major Medicare payment system that does not include a teaching adjustment. Teaching adjustments are included in the inpatient, psychiatric and rehabilitation facilities prospective payment systems. We urge CMS to conduct a study to determine whether teaching hospitals incur higher outpatient service costs compared to other hospital types, thereby supporting the addition of a teaching adjustment to the OPPS.

The outpatient department is critical to fulfilling the missions of teaching hospitals. In addition to providing a site for clinical education for all types of health professional trainees, teaching hospital outpatient departments provide an environment in which clinical research can flourish, and are a source for specialized, unique, and referral/standby services. Because of their education and research missions, teaching hospitals offer the newest and most advanced services and equipment, and care for the nation's sickest patients. In addition, teaching hospital outpatient departments often serve as a primary source of health care for low-income Medicare beneficiaries and other disadvantaged individuals.

In the initial OPPS Final Rule, published April 7, 2000, CMS stated that it would "conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire." (65 Fed. Reg. at 18500). In addition, the Balanced Budget Act of 1997 requires the Secretary to establish adjustments "as determined to be necessary to ensure equitable payments . . . for certain classes of hospitals." (Section 4523 of the BBA).

In the 2006 final rule however, CMS asserted it does not believe "that a study of unit costs of teaching hospitals relative to other classes of hospitals is necessary at this time," because "such studies are especially warranted when hospitals experience a negative increase in payments" and for CY 2006 "major teaching hospitals are projected to experience an overall increase in payments of 1.0 percent." However, those statements were just that – assertions. We believe CMS has an obligation to do full data analysis because Medicare outpatient margins, while negative for all hospitals, are significantly lower for major teaching hospitals than for other teaching and nonteaching hospitals. For example, according to an internal analysis of 2004 hospital Medicare cost reports, the average outpatient margins were -20.2 percent for major teaching hospitals, -10.1 percent for other teaching hospitals and -11.8 percent for nonteaching hospitals.

In light of the negative margins, as well as the BBA requirement and CMS's commitment to make payment adjustments for classes of hospitals that may be negatively impacted by the OPPS, the AAMC believes that it is incumbent upon CMS to conduct a comprehensive analysis that would include the impact of the costs associated with teaching hospitals' teaching and research missions on their outpatient cost structure. If

such an analysis concludes that teaching hospitals have higher costs, we believe a teaching adjustment should be included.

QUALITY REPORTING UNDER THE OPPS

The Tax Relief and Health Care Act (the Act) that was passed in December 2006 modified the payment update for OPPS payments for services provided by hospitals in outpatient settings starting January 1, 2009. The Act required the establishment of a quality reporting program for the hospital outpatient setting and mandates hospitals to submit quality data on hospital outpatient performance measures. The penalty for not submitting quality data will be a reduction in the annual payment update factor by 2.0 percentage points. In order to meet the January 1, 2009 deadline, the proposed rule requires hospitals to submit data on the final measure set beginning January 1, 2008.

The AAMC and its hospital and physician members are committed to delivering quality care to our patients and taking responsibility for the care we provide. As founding members of the Hospital Quality Alliance (HQA), the AAMC has been at the forefront of making hospital performance data available to the public to help inform patient decision-making. To that end, we are supportive of providing performance data to patients regarding their care in the hospital outpatient setting. However, we have serious concerns with the implementation plan that is proposed.

When the inpatient quality reporting program was created, an established framework and process for data collection and submission existed. There is no such framework or process for the outpatient setting. Creating a new data collection process within the hospital, as well as modifying data vendor contracts to accommodate outpatient data is both time consuming and costly. This is further compounded by the fact that the implementation schedule for this program is extremely aggressive.

Based on our concerns and the implementation challenges outlined below we propose that CMS utilize a phased-in approach. Since the legislation only requires hospitals to submit their data for payment determination in CY 2009, CMS could technically delay the reporting deadline a few months. This would allow time for further field testing, final measure specifications, appropriate time to develop new processes for the hospitals and vendors and establish a general comfort level for this new reporting stream. Alternatively, CMS could begin data collection with the Emergency Department measures where there is more familiarity and dexterity in data collection given the inpatient measures for the Emergency Department and then phase-in the other ambulatory measures where additional time and experience are crucial.

Implementation issues

In order for performance measures to be implemented on a national basis they need to be endorsed by the National Quality Forum (NQF), be evidence based, and be fully specified and adequately field tested for validity and reliability. The measures included

in this program have only been through very basic testing and not on a national basis. We understand that CMS is finalizing plans to conduct further field testing which we applaud, however the details of the testing are not yet known and will potentially further delay the point at which the measure specifications can be finalized.

Hospitals need finalized measure specifications to make appropriate resource and information technology determinations in order to collect the necessary data. The measure specifications that have been released are not final and therefore are not actionable. As stated previously, any further field testing will introduce delays and possible changes to the measures and will impact the hospital's ability to begin data collection by the proposed January 1, 2008 deadline.

In addition to the hospitals, the data vendors that support the hospitals need final measure specifications with the appropriate amount of time in order to program for data collection. Most of our members would like to be able to utilize their Joint Commission ORYX vendors for both inpatient and outpatient reporting which would be efficient for the hospitals, and would ensure data validation and vendor assessment through the ORYX program. However, vendors have expressed their concern and reluctance to make a decision to participate in outpatient data collection due to the current ambiguity regarding final measure specifications as well as the compressed timeline to program their systems. If vendors are not willing to participate then the necessary data collection infrastructure is lacking, leaving hospitals with limited options for efficient and cost-conscious solutions.

Measures

We are in support of the initial proposed measures; however, we do have concerns regarding the diabetes measure because it is an outcome rather than a process measure. At the outset, we appreciate CMS's recognition of the attribution issue associated with this measure for multi-specialty clinics by requiring the submission of data on this measure for primary care specialties only.

We agree that a diabetes measure is important for determining improvements in the management of diabetes patients. However, many of our outpatients are unable or unwilling to adhere to the prescribed care. Consequently, the ability to control a patient's Hemoglobin A1c level is not always within the control of the physician/resident/clinic. In addition, the ability to control the hemoglobin level becomes more difficult for difficult and complex patients. Including some form of risk adjustment to recognize these cases would ensure fairness for those hospitals that treat these patients.

As far as future measures, we believe that CMS should only use those measures that are approved by the HQA. This is reinforced in the legislation, which states that the measures must reflect consensus among the affected parties.

Administrative Issues

In order to reduce additional administrative burden as well as increase efficiency, we are asking that hospitals that are submitting data for both the inpatient program as well as the outpatient program be able to submit one Participation Form. Utilizing two forms just adds to confusion and potential error.

The initial year of the inpatient reporting program did not include validation testing, in part, to allow the hospitals to gain experience with the program. We would like to suggest the same approach for the outpatient program. Once an appropriate level of experience has been gained, then the validation testing should be resumed.

We have stated in previous inpatient PPS comment letters that the Central Data Abstraction Center (CDAC) should not have the authority to both pull the charts required for validation as well as be responsible for the re-abstraction. These responsibilities should be separated and handled by two separate entities.

Finally, as academic medical centers with large numbers of hospital outpatient clinics as well as faculty practices, we would like to strongly advocate for coordination between hospital and physician initiatives. The measures in the outpatient program are similar to the measures for the physician reporting initiative, yet require different data collection mechanisms. If these efforts are not coordinated on an ongoing basis, it will place an additional and unnecessary burden on the hospitals and physicians.

PROPOSED PACKAGING APPROACH

Currently, services within the ambulatory payment classification (APC) groups reflect only a modest degree of "packaging" and very little "bundling." Packaging refers to the extent to which payment for minor, ancillary services associated with a significant procedure is "packaged" with the primary procedure and receives a single APC amount. Bundling refers to the extent to which payment for multiple, significant procedures related to an outpatient encounter or episode of care is "bundled" and receives a single APC amount. For the most part, the OPPS currently makes a separate payment for each individual service provided during a hospital encounter.

For CY 2008, CMS is proposing to expand packaging and bundling, so that more services that are currently paid separately would receive a single APC payment, thereby decreasing the number of APC payments that a hospital would receive. Specifically, CMS is proposing to package the costs of minor, ancillary services that fall into any of the following seven specified categories that are associated with significant procedures into a single payment for the significant procedure.

1. Guidance services
2. Image processing services
3. Intraoperative services

4. Imaging supervision and interpretation services
5. Diagnostic radiopharmaceuticals
6. Contrast media
7. Observation services

The Agency also is proposing to create two "composite APCs" by bundling multiple significant procedures related to two outpatient encounters, one for Low Dose Rate (LDR) Prostate Brachytherapy and the other for Cardiac Electrophysiologic Evaluation and Ablation. CMS believes that increasing the payment bundles through both increased packaging and the creation of composite APCs, will lead to efficiencies in the hospital outpatient departments, because it would create incentives for hospitals to use the least expensive items that meet the patient's needs and to negotiate more vigorously with manufacturers and suppliers to reduce the cost of purchased items and services.

Although we are supportive of CMS's efforts to increase efficiency in care delivery, we are concerned that the packaging proposal has not been thoroughly analyzed and the impact on hospitals still needs to be determined. For example, CMS has not released all the data for hospitals to be able to conduct their own analyses, including providing a crosswalk between the current APCs and the new "packaged" APCs.

Under the proposed rule, the median costs for many procedures will change as a result of increased packaging. CMS notes that median costs may go up, but may also stay the same or go down due not only to increased packaging but also due to the migration of HCPCS codes into and out of APCs as well as a change in the number and composition of claims CMS uses to establish APC median costs.[1] Furthermore, while the proposed rule states that the estimate of payment redistribution that would result from its packaging proposal is approximately 1.2 percent of the estimated CY 2007 base year expenditures under the OPPS, analyses sponsored by the American Hospital Association indicate that the seven categories in the proposed rule represent six percent of outpatient costs. These factors highlight the need for the public to study and understand the methodology used in determining how the costs of packaged services have been assigned to a specified APC and the level of costs assigned to an APC.

It is the AAMC's position that any major policy change, such as the one proposed, needs to be transparent and the methodology and impacts clearly understood by the hospitals affected. Therefore, although CMS's impact analysis shows that, in the aggregate, the packaging approach would have a positive impact on major teaching hospitals, we urge CMS to reevaluate its proposal. If the Agency decides to proceed with implementation, we urge the Agency to exclude observation services (see below) from the final rule.

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[1] According to CMS, greater packaging led to more "natural" single bills for some codes and fewer "pseudo" single bills for others. As a result, some APCs gain while others lose single bills. Thus, for each APC, the use of more or less claims from a different mix of providers can increase or decrease the median cost of that APC.

Observation services

Observation is an important component of patient care delivery as it allows hospital staff to monitor and assess patients' conditions. Thus, any policy involving changes to these services must be carefully considered and the implications fully understood.

The AAMC is concerned that packaging the costs of all observation services without further analysis of the claims data and methodology used to determine the primary procedures to which they have been assigned could have negative consequences on health care delivery for both outpatient and inpatient services.

CMS is proposing to package the cost of observation services reported under HCPCS code G0378 (Hospital observation services, per hour) into the separately payable services with which the observation services are billed. That is, the cost of observation services provided to patients with any one of three diagnoses (congestive heart failure, chest pain, or asthma) will be packaged into payment for the primary procedure with which they are billed.

Since 2002, when CMS implemented separate payment for observation services, hospitals have found the billing requirements confusing and administratively burdensome. The Agency and the APC Advisory Panel have since been working with providers to clarify and simplify the billing process for separately payable observation services. Hospitals have been working to comply with the billing requirements, but the confusion spanning a number of years has led to inconsistent billing among hospitals, which in turn has resulted in poor data. Using these data to determine how to package observation services could reduce payment for these vital services and could alter care delivery by potentially increasing hospital admissions.

Furthermore, as the proposed rule notes, the Institute of Medicine's (IOM) committee on the future of Emergency Care in the U.S. recommends that CMS remove current limitations on medical conditions that are eligible for separate observation care payment. This would encourage the development of observation units that may improve the flow of patients through overcrowded emergency departments.

The AAMC strongly recommends that CMS provide hospitals with the data showing how observation services have been assigned to APCs. This is necessary to ensure that the proposed methodology of assigning packaged services to primary procedures found on the claim leads to the creation of APCs that are clinically coherent and have appropriate payment rates. In light of these concerns, we urge CMS to delay its packaging proposal for observation services until the public has the opportunity to understand the full implications of this policy.

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Separate Reporting of Pharmacy Overhead Charges

For CY 2008, CMS is proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological with which it is associated and instead report the pharmacy charge on an uncoded revenue code line on the claim. CMS intends to collect pharmacy overhead costs and package them into payment for the procedure associated with administering the drug or biological rather than into the payment for the drug or biological. The Agency believes this proposal would improve its packaging efforts.

The AAMC appreciates CMS's effort to try to find better ways to account for pharmacy overhead costs. However, the proposed policy of removing the overhead charges from the charge for the drug or biological and report it on an uncoded revenue code line will not accomplish this goal. This is because the proposed policy is practically untenable due to the administrative burden it would impose on hospitals and is likely to result in poor data.

As our members have pointed out, this proposed policy, if implemented, would require a major overhaul of coding and billing systems for hospitals. If hospitals are required to report overhead charges separately from the charge of the drug, it would require them to invest in separate stand-alone computer systems, that would maintain two charges for each of the potentially thousands of drugs to be charged. For bills to non-Medicare payers, this stand-alone system would have to add the two charges together before posting to the bill, while for Medicare bills, the system would simply pass the individual charges for each drug to the bill, and add together all of the overhead charges and pass this latter charge to an un-coded line on the Medicare bill.

The systems hospitals have now are not set up differently based on the type of payer and it is unlikely that they could be, at least in the short term. Making the changes envisioned by the proposed rule would be expensive, administratively burdensome and would take time to implement as hospitals would have to determine how to establish new charges for pharmacy overhead and to develop extensive training programs to educate the staff in all areas of the hospitals where drugs are administered and dispensed.

Furthermore, the proposed rule does not include any guidance as to what constitutes overhead and handling costs. Thus, without knowing what revenue codes should be used to report the information on the uncoded line, each hospital may use different revenue codes, resulting in highly variable and inaccurate data for the purpose of determining overhead and handling costs.

In sum, while we support CMS's effort to continue to determine pharmacy overhead costs, we strongly oppose the proposed separate reporting of pharmacy overhead costs.

The AAMC and our members would be happy to work with CMS to identify ways to obtain these data in a way that is more administratively feasible.

Proposed Payment for Separately Payable Drugs and Biologicals

Relying on hospital cost reports and outpatient claims data to estimate costs, CMS is proposing to pay for separately payable drugs and biologicals at the average sales price (ASP) plus five percent. This constitutes a one percent payment reduction from the payment rate hospitals receive in 2007. It also is lower than the physician office setting payment rate of ASP plus six percent.

We urge the Agency to continue to provide payment for separately payable drugs and biologicals at ASP plus six percent. This would provide a consistent payment policy across providers and increase the likelihood that hospitals receive adequate payment that covers drugs and biologicals and their associated handling costs. Providing consistent payments across providers has been CMS's long-standing policy that was implemented in part to discourage providers from treating patients in one setting over another.

The AAMC remains concerned however, that even the current rate of ASP plus six percent is inadequate at covering the acquisition and handling costs of separately payable drugs and biologicals and urges CMS to conduct further analyses of its methodology for setting payment rates based on acquisition costs.

EVALUATION AND MANAGEMEN (E/M) GUIDELINES

Since the implementation of the OPPS and through CY 2006, hospitals have been reporting five resource-based coding levels for clinic visits and five coding levels for emergency department visits using CPT E/M codes. The least and most resource intensive codes were combined resulting in three APC payment levels.

In CY 2007, CMS started to pay for clinic visits and emergency department visits using five rather than three levels of payment, based on the assignment of the codes to five clinic visit APCs and five emergency department visit APCs.

Because the CPT E/M codes were designed for physician payments, CMS believes that they may not adequately describe the range and mix of services provided by hospitals during these encounters. Consequently, CMS has allowed hospitals to use their own internal guidelines to determine which CPT level code to report. As a result, each hospital currently uses its own guidelines to code for clinic and emergency department visits.

Since 2003, CMS has worked with stakeholders as well as an independent panel consisting of experts from the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) to develop national guidelines that would provide consistency in the coding methodology used by various hospitals.

To date, the Agency has not developed national guidelines, but continues to study the issue. Until the national guidelines are developed, CMS is proposing to allow hospitals to continue to use their own guidelines.

In the proposed rule, the Agency sets forth principles that CMS expects hospitals should follow in developing internal guidelines. The AAMC is concerned about a potential confusion that may arise in interpreting the second principle which states "The coding guidelines should be based on hospital facility resources. The guidelines should not be based on physician resources." (72 Fed. Reg. 42765)

Hospitals have been using internal coding guidelines for clinic visits since the November 1, 2002 final rule. In that final rule, CMS did not explicitly prohibit hospitals from using physician codes to code for hospital visits. Rather, the rule specifies that hospitals not use codes based on physician resources "Facilities should code a level of service based on facility resource consumption, not physician resource consumption." (67 Fed. Reg. 66793)

Consequently, if a hospital determines that the hospital level resources correlate with the physician codes, there is no reason why the physician codes cannot form the basis of the hospital's internal guidelines. In the final rule we would like CMS to confirm that hospitals may continue to use physician coding guidelines if they see fit. Such guidelines would continue to meet the principles set forth by CMS including the second principle stating that the guidelines be "based on hospital facility resources."

If CMS, however, now believes hospitals should not base their internal guidelines on the physician coding guidelines, we urge the Agency to propose such a change formally, along with the rationale for the policy change, next year when it issues its proposed rule. We note, however, that we believe such a proposal would be unwise in that, if it were finalized, among other issues, it would be administratively burdensome, if not untenable in the short run, for affected hospitals to develop brand new guidelines. Moreover, it would not eliminate the variation that already exists among hospitals because each has developed its own set of internal guidelines. Finally, if national coding guidelines are developed at some point in the future, these hospitals would again need to change their coding guidelines.

DEVICE-DEPENDENT APCs

In recent years, some devices have been recalled and the manufacturers have offered replacement devices at no cost to the hospital or a credit for the device being replaced if the patient received a more expensive device. Thus, for CY 2007, in order to identify devices for which the hospital incurs no expense for a defective device that has been replaced, and to set payment rates for device-dependent APCs that contain such devices,

CMS requires hospitals to use modifier "FB" for procedures that use these devices and applies a payment reduction to those procedures that is based on an estimate of the device cost.

CMS is proposing to expand its policy to reduce the APC payment for selected device-dependent APCs when the hospital receives a partial credit when a defective device is replaced. Thus, under the proposed rule, the Agency would require hospitals to report a modifier for those cases in which a hospital receives a partial credit toward the replacement of a defective device.

The proposed rule would reduce the payment for the device-dependent APCs associated with devices for which hospitals have received partial credit for their replacement by half the reduction (half the offset amount) that applies when the hospital receives a device at no cost or receives full credit. CMS is proposing to apply this policy only in those cases in which the amount of the device is greater than or equal to 20 percent of the cost of the new replacement device being implanted.

While we understand the rationale for this proposal, especially since it was implemented in 2007 for replacement devices without cost to the hospital or when the hospital receives a full credit for the device, we believe that the additional administrative burden imposed by this proposal on hospitals, in the form of the significant number of claims that must be re-billed in conjunction with replacement devices for which the hospital receives only partial credit is not justified by the potentially insignificant savings to the OPPS program as a whole. On page 42724 of the proposed rule, in the discussion of hospitals that do not reduce charges for devices upon which they receive partial credit, CMS states, "It is likely that the reduced hospital costs associated with steady, low volume warranty replacements of implantable devices may never be reflected in the cost-to-charge ratios (CCRs) used to adjust charges to costs for devices, because those CCRs are overwhelmed by the volume of other items attributed to the cost centers." This statement seems to suggest that credits for replacement devices are insignificant in relation to the median costs for the all devices being adjusted.

The additional reporting burden on hospitals arises from probability that 50 percent or more of all situations involving replacement devices for which the hospital receives partial credit will require the hospital to re-bill the procedure to Medicare. Many vendors require the failed device be returned to them for examination and evaluation before any credit is granted to the hospital. Thus, at the time a hospital bills Medicare for a procedure to replace a failed device, the hospital does not know the amount of a possible credit it may or may not receive on the returned device. The hospital does not know the amount of any such credits for one to three months after the procedure is performed, and thus will have to re-bill Medicare when the credit is received. The whole process of applying billing adjustments for such "device return credits" is highly manual. The common billing and charge systems used by most hospitals do not have an automated interface with the materials management systems which may track and record the device returns and credits. Also, given the infrequency of these returns, it is highly unlikely that

most materials management systems track these returns and credits in an automated fashion at all. It is not common for material management departments to routinely match purchases and return data with specific patients, which must be done to apply billing adjustments required by the Medicare billing requirement implemented for 2007. This proposal would make the billing requirements even more burdensome for hospitals without resulting in significant savings for the Medicare program.

Thus, we urge CMS to apply a similar policy to that adopted in the FY 2008 final inpatient rule. In that rule, CMS implemented a payment policy that reduces payment for DRGs in which the hospital receives credit equal to 50 percent or more of the cost of the device. In order to address hospitals' concerns regarding the administrative burden and proper billing, CMS gave hospitals two options: 1) submitting the claims immediately without the special condition code (Condition Code 49 under the inpatient PPS) and then submitting a claim adjustment with the condition code at a later date once the credit determination is made, or 2) holding the claim until a determination is made on the level of the credit. The AAMC urges CMS to give hospitals the same billing options under the OPPS as they have under the inpatient prospective payment system.

NEW TECHNOLOGY APCs

CMS is proposing to move certain procedures from "new technology APCs" to clinical APCs in less than two years. A number of these procedures will experience payment reductions due to these new assignments. Although it is the purview of CMS to move services from new technology APCs to clinical APCs in less than two years, we are concerned that the data that CMS obtains in the first two years after services are approved may not be accurate because diffusion of new technologies can be slow and hospitals need time to update their charge masters to appropriately reflect charges that reflect the actual costs of the new services. We ask CMS to consider maintaining procedures in the new technology APC categories for a minimum of two years before assigning them to a clinical APC.

* * * * * * * * * *

Teaching hospital's outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the mission of teaching hospitals. Medicare outpatient payments are critical for teaching hospitals to continue their missions in the outpatient setting, including serving important access roles for outpatient services that range from clinic and emergency room visits to technically-advanced innovations. We would be pleased to work with CMS as it continues to refine and improve this important Medicare payment system.

If you have questions concerning these comments, please contact Diana Mayes, at dmayes@aamc.org, 202-828-0498 or Karen Fisher at kfisher@aamc.org, or 202-862-6140. You may also contact Jennifer Faerberg at jfaerberg@aamc.org or 202-862-6221 for quality-related questions.

Sincerely,

Robert Dickler

cc: Karen Fisher, AAMC
Diana Mayes, AAMC
Jennifer Faerberg, AAMC

The Alliance for Better Bone Health

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September 14, 2007

VIA HAND DELIVERY AND ELECTRONIC SUBMISSION

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

RE: CMS-1392-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates)

Dear Acting Administrator Weems:

The Alliance for Better Bone Health (the Alliance) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS') proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on August 2, 2007 (the "Proposed Rule").[1] Procter & Gamble and Aventis formed the Alliance in May 1997 to develop and market Actonel collaboratively in Europe, the United States and Canada. The Alliance promotes bone health and disease awareness through numerous activities to support physicians and patients around the globe.

Osteoporosis has a significant fiscal impact on the Medicare program, and studies suggest that testing for and treating the condition could reduce program costs.[2] In addition, the Medicare population accounts for an estimated 87 percent of the osteoporosis-related fracture costs in the U.S.[3]

We believe that by including osteoporosis quality measures in the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), CMS could improve patient care and reduce Medicare costs. We outline below our support for the proposed use of the four osteoporosis measures from the Physician Quality Reporting Initiative (PQRI) in the HOP QDRP. In addition, we request that CMS consider distinguishing between DXA testing and pharmacologic therapy in the specifications of the HOP QDRP osteoporosis measures in order to promote prevention of fragility fractures.

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[1] 72 Fed. Reg. 42627 (August 2, 2007).
[2] Newman et al., JCOM 2003; King et al., Ost Int 2005; The Lewin Group 2007.
[3] Burge et al., JBMR 2007.

I. CMS Should Include the Four PQRI Osteoporosis Measures in the HOP QDRP Measure Set [QUALITY DATA]

We strongly agree with CMS' assessment that the following four osteoporosis measures would be appropriate quality measures for the outpatient setting:

1. Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture (PQRI #24);
2. Osteo-02: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older (PQRI #39);
3. Osteo-03: Management Following Fracture (PQRI #40); and
4. Osteo-04: Pharmacologic Therapy (PQRI #41)

We do, however, urge CMS to adopt the measures for inclusion in the CY 2008 measure set rather than waiting until CY 2010.

These four osteoporosis measures are currently used in the physician office setting, and one (osteoporosis management following fracture) has been used by Medicare Advantage plans for several years. The NQF has endorsed the four measures for two years, until May 8, 2009.[4] These same four measures were part of the 2008 measure set proposed by CMS for use in the PQRI program.[5] We believe these are precisely the types of measures that can be applied in both the physician office and hospital outpatient settings. By including the same measures in both the PQRI and the HOP DQRP measure sets in 2008, CMS could promote the laudable goal of maximizing harmonization across care settings. We support providing incentives for reporting on these measures because that may change care patterns, potentially leading to improved screening, diagnosis, and management of osteoporosis.

We do not believe there are reasons for waiting until CY 2010 to include these measures in the HOP DQRP measure set, but rather urge CMS to prioritize their inclusion for 2008 reporting. Osteoporosis is a condition that affects the Medicare population significantly, and there is evidence of the underdiagnosis and undertreatment of osteoporosis in older people.[6] CMS should take the opportunity to encourage screening for fracture risk, particularly since the relationship between bone density and fracture is stronger than the relationship between cholesterol and heart attack.[7] After the expansion of coverage in 1998, Medicare bone mass measurement became more frequent, but the rate of testing growth has slowed recently.[8] Although the U.S. Preventive Services Task Force recommends routine osteoporosis screening in women aged 65 years and older,[9] less than 10 percent of female Medicare beneficiaries received a Medicare-reimbursed DXA test in 2006.[10]

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[4] 72 Fed. Reg. at 42801-02.
[5] 72 Fed. Reg. 38122, 38201-02 (July 12, 2007).
[6] US Surgeon General, Bone Health and Osteoporosis, 2004.
[7] Marshall et al. BMJ 1996.
[8] King et al. Ost Int 2005.
[9] Ann Int Med 2002.
[10] CMS ORDI, BESS data, August 2007.

We emphasize that both screening and treatment need to be encouraged. HEDIS data for 2005 indicated that only 20 percent of women in Medicare Advantage plans were either tested or treated for osteoporosis in the six months following a fracture.[11] Diagnosis of osteoporosis does not always lead to treatment, even for high-risk patients who already have experienced fractures.[12] For these reasons, we hope that CMS will continue to have separate measures for osteoporosis screening and therapy.

II. CMS Should Distinguish Between DXA Testing and Pharmacologic Therapy in the Osteoporosis Measure Specifications [QUALITY DATA]

CMS should promote the prevention of fragility fractures by distinguishing DXA testing from pharmacologic therapy in the HOP DQRP measure specifications. We recommend that reporting include data on the subgroups with DXA testing ordered, those for whom treatment was prescribed, and the total number of patients. CMS already is collecting data that distinguish which patients are tested and which are treated, because separate CPT II codes are used. Reporting of this information will enable better feedback on quality of care, as well as evaluation of whether CMS policies or medical interventions differentially affect testing and treatment rates at the aggregate level.

III. Conclusion

We appreciate the opportunity to comment on these important issues and thank CMS for considering our suggestions for strengthening Medicare payment policies and quality initiatives to improve preventive care for patients at risk for fragility fractures. Please contact Alison King at 607 836-6675 if you have any questions on these comments.

Sincerely,

Ed Greissing
Vice President, U.S. Communications
& Federal Government Relations
Sanofi-aventis Pharmaceuticals
Bridgewater, NJ 08807

Alison B. King, Ph.D.
Public Policy & Government Relations
Procter & Gamble Health Care
Mason, OH 45040

[11] NCQA, The State of Health Care Quality, 2006, Washington, DC.
[12] King et al Ost Int 2005; Pressman et al. Ost Int 2001; Klotzbuecher et al. JBMR 2000, Johnell et al. Ost Int 2004.

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RECEIVED - CMS

September 14, 2007 2007 SEP 14 P 3:19

BY HAND DELIVERY AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS 1392-P; Comments Regarding the Proposed Hospital Outpatient Prospective Payment System Rule for Calendar Year 2008

Dear Mr. Weems:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the Medicare Hospital Outpatient Prospective Payment System Proposed Rule for 2008 published by the Centers for Medicare and Medicaid Services (CMS).[1] Astellas is among the top 20 global research-based pharmaceutical companies, with global sales of approximately $8 billion, and the number two Japan-based pharmaceutical company. Our fundamental goal is to use our expertise in key therapeutic areas to improve the health of Americans by developing and marketing cures for unmet medical needs. Our North American product lines, which focus on the therapeutic areas of infectious disease, immunology, cardiology, dermatology, and urology, are used by Medicare beneficiaries in a variety of settings, including hospital outpatient departments.

Our comments are set forth below.

* * *

[1] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates, 72 Fed. Reg. 42628 (August 2, 2007) (the Proposed Rule).

I. SPECIFIED COVERED OUTPATIENT DRUGS (SCODS)

Payment for SCODs[2] in CY 2006 and subsequent years must equal the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005.[3] CMS currently pays for SCODs at 106% of ASP. For 2008, however, CMS has proposed to pay for SCODs (including their acquisition costs and associated overhead costs) at 105% of ASP. CMS developed this proposal by comparing two sources of data: ASP data from the fourth quarter of CY 2006, and mean costs derived from the CY 2006 hospital claims data.[4] Based on these data, CMS concluded that using mean cost to set SCOD payment rates would be "equivalent to basing their payment rates, on average, at ASP+5 percent."[5]

CMS had initially proposed a SCOD payment rate of 105% of ASP for 2007, but did not finalize the 105% of ASP rate in 2007. Instead, CMS decided, "after carefully considering all comments and the recommendations of the APC [Ambulatory Payment Classification] panel," that it would accept the Panel's recommendation to continue paying for SCODs and their associated overhead costs at a combined rate of 106% of ASP.[6]

CMS maintained the 106% of ASP rate for SCOD acquisition and overhead costs during 2007 for several reasons: (1) because the "[2007] final rule analysis [of mean costs derived from hospital claims data] indicated an average ASP-based payment of ASP + 4 percent," which was "the same relative ASP-based amount that was comparable to the GAO purchase price data for a subset of drugs reviewed in our CY 2006 final rule with comment period, which did not include pharmacy overhead costs";[7] (2) to "maintain[ ] stability in the payment levels for drugs and biologicals . . . in light of the inherent complexity in determining how best to account for pharmacy overhead costs;"[8] (3) to gain a "better understanding of the full nature and magnitude of hospitals' costs related to these important [overhead] activities;"[9] and (4) because the 106% of

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2 A SCOD is a drug for which a separate APC has been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002. SCODs do not include drugs that first received pass-through payments on or after January 1, 2003, and drugs that have not been assigned a temporary HCPCS code. Social Security Act (SSA) § 1833(t)(14)(B).

3 SSA § 1833(t)(14)(A)(iii).

4 72 Fed. Reg. at 42736.

5 Id.

6 71 Fed. Reg. 67960, 68091 (November 24, 2006).

7 Id. (emphasis added).

8 Id.

9 Id.

ASP rate would "ensure suitable payment for the hospital pharmacy overhead costs associated with drugs and biologicals," while CMS "continue[d] to work with the hospital industry to understand the complex issues related to capturing and evaluating these overhead costs."[10]

The CY 2008 Proposed Rule reflects the same approach to setting the proposed payment for acquisition and overhead costs for separately payable SCODs that CMS used in the CY 2007 Proposed Rule (i.e., choosing an ASP-based payment percentage based on mean costs derived from hospital claims data). Unlike the 2007 Proposed Rule, CMS has not offered a rationale as to why this approach might capture pharmacy overhead costs as well as drug acquisition costs. CMS has also proposed a method to collect data on pharmacy overhead costs beginning in 2008, by having hospitals include pharmacy overhead costs on an uncoded revenue code line on the claim. However, the 2008 Proposed Rule does not suggest that any of the factors that prompted CMS to maintain the 106% of ASP payment rate for 2007 have changed in any way. The proposal to collect data on overhead costs through revenue center coding (assuming it is finalized and implemented) will not produce any data on pharmacy overhead costs relevant to 2008 payments. Consequently, until CMS has collected accurate data on pharmacy overhead costs, it should continue to pay 106% of ASP for SCODs, for all of the reasons listed above that appropriately led CMS to the decision to pay 106% of ASP for 2007.

During the March 2007 APC meeting, the APC Panel recommended that "the overhead payments be made in addition to the current ASP + 6 percent payment rates for separately payable drugs."[11] If CMS does not accept that recommendation, it should at a minimum maintain the 106% of ASP payment rate until accurate data becomes available on pharmacy overhead costs in order to promote payment stability and beneficiary access. Accordingly, Astellas urges CMS to maintain the current 106% of ASP rate for 2008, as the Agency works with hospitals to collect data on pharmacy overhead costs. This approach will avoid the risks of arbitrary cuts in payment for important drug therapies and help to maintain Medicare beneficiaries' access to the most appropriate care.

II. OPPS: PACKAGED SERVICES

CMS proposes to package payment for "image processing" HCPCS codes -- i.e., "specifically those codes that are reported as dependent services to process and integrate diagnostic test data in the development of images, performed concurrently or after the independent service is complete."[12] One specific example described in the Proposed Rule is the proposed packaging of CPT 93325 Doppler color flow add-on with CPT 93350 Echo

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[10] Id.

[11] 72 Fed. Reg. at 42735.

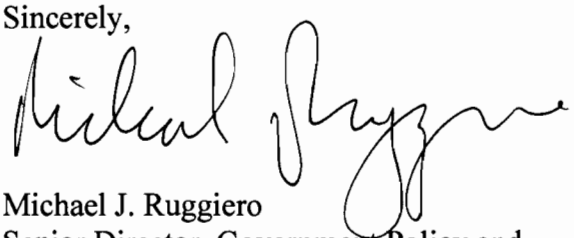
[12] 72 Fed. Reg. at 42657.

transthoracic and CPT 93017 Cardiovascular stress test. We understand that the status of CPT 93325 may be in flux at the CPT Editorial Panel. We urge CMS to maintain the status quo in the OPPS until interested physician specialty societies can fully resolve any coding issues prior to CMS considering changes in the payment status for these codes.

* * *

Astellas appreciates the opportunity to provide these comments. If you have any questions or would like additional information, please contact me at 202-812-6162 or via e-mail (michael.ruggiero@us.astellas.com).

Sincerely,



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September 14, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
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200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P; Medicare Program; Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Rule; OPPS: Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Dear Acting Administrator Weems:

Amgen Inc. (Amgen) is writing regarding the calendar year (CY) 2008 Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule (Proposed Rule), which the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register on August 2, 2007.[1]

As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicare beneficiaries. For this reason, we provide relevant information below on the "Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals" section of the Proposed Rule as it applies to all separately payable drugs and to our innovative biological product, Aranesp® (darbepoetin alfa), in particular.[2]

Amgen commends the agency on its continued use of a market-based approach to set the OPPS payment rates for separately payable drugs, including Aranesp®. The proposed average sales price (ASP) based payment methodology for separately payable drugs allows the payment rates for these products to reflect market dynamics and encourages the desired market adaptations that manufacturers and hospitals make to remain competitive. Regarding Aranesp® in particular, we are pleased that CMS continues to apply its free market-based approach and does not discuss, solicit comments on, or propose applying an "equitable adjustment" to establish the 2008 OPPS payment rate for Aranesp®.

In the 2006 and 2007 Final Rules, CMS specifically addressed its rationale for not applying an "equitable adjustment." In particular, CMS noted in the 2007 Final Rule its "intent to permit market forces to determine the appropriate payment rate for [Aranesp®]" and noted that equitable adjustment would not lead to a different result "as long as the market price for [Aranesp®] is consistent with a payment rate derived using a clinically appropriate conversion ratio".[3] For these reasons, CMS did not apply an "equitable adjustment" under Section 1833(t)(2)(E) of the Social Security Act to the payment rate of Aranesp® in Calendar Year 2007. In the 2008 Proposed Rule, CMS continues the existing policy.

Below, we present further evidence to support the current treatment of separately billable drugs in general and Aranesp® in particular under the Proposed Rule.

COMMENTS ON SPECIFIED COVERED OUTPATIENT DRUGS

Amgen supports the proposed ASP-based payment methodology for drugs and encourages CMS not to reduce the ASP + 6 percent payment, as proposed.

ASP is designed to reflect the average cost of purchasing a specific drug across purchasers. As such, we have supported the ASP methodology and market-based pricing.[4] However, we are concerned with the agency's proposal to reduce payment from ASP + 6 percent to ASP + 5 percent. CMS uses the same data analysis methodology that it employed in last year's Proposed Rule (and then rejected in the Final Rule) to arrive at the proposed level of payment. In fact, the 2008 Proposed Rule does not indicate how the circumstances that led CMS ultimately to accept the recommendations of the Ambulatory Payment Classification (APC) panel to maintain payment at ASP + 6 percent for CY 2007 have changed for 2008. Further, at its most recent public hearing, the APC Panel continues to recommend that CMS continue to reimburse separately covered outpatient drugs at the current ASP + 6 percent.[5]

The agency should also consider the appropriateness of having the same products paid for at differing rates in similar settings of care (*i.e.,* proposed ASP + 6 percent payment in the physician office setting versus proposed ASP + 5 percent payment in the hospital outpatient setting) and whether this could lead to inappropriate shifts in access to care across clinical settings.

For these reasons, we urge CMS to set the reimbursement rates for specified covered outpatient drugs at ASP + 6 percent.

By continuing the use of market-based pricing and not applying an "equitable adjustment" to the payment rate for Aranesp®, Medicare and its beneficiaries will pay about the same or less for comparable clinical outcomes.

For several years before the implementation of the 2006 Final Rule, OPPS payments for separately payable drugs were determined under different methodologies, and CMS had applied an "equitable adjustment" using a controversial dose conversion ratio. With the implementation in 2006 of market-based payment rates for all separately payable

drugs, including Aranesp®, it became clear that an "equitable adjustment" was not needed, particularly given the comprehensive evidence of the comparable costs and outcomes of Aranesp® and Procrit® at the most commonly used doses. Since CMS proposes to continue using market-based pricing in 2008, the agency correctly does not propose an "equitable adjustment" in the case of Aranesp®, nor does the agency discuss or solicit comments on applying an "equitable adjustment" to any drug in the Proposed Rule. As demonstrated by our previous submissions, there is a wealth of clear and compelling clinical and economic data to support the agency's decision not to apply an "equitable adjustment" for Aranesp®.

The treatment of Aranesp® under the Proposed Rule is fully consistent with well-established clinical practice guidelines, which have been validated by randomized, comparative clinical trials. Amgen's clinical submissions to CMS from 2003 through 2006 demonstrated that Aranesp®, when used in accordance with these guidelines, achieves comparable clinical outcomes at the same or lower cost to Medicare, when compared with commonly administered doses of Procrit®.[6,7,8,9]

Since our submission on the 2007 Proposed Rule, there has been additional evidence demonstrating that Aranesp® and Procrit® achieve comparable clinical outcomes at comparable costs to Medicare. Furthermore, since the adoption of the ASP methodology, Medicare has paid less than or about the same for Aranesp® than for Procrit®. This statement holds true for the payment rates that CMS has published in the Proposed Rule for clinically comparable doses and dosing regimens.

Importantly, Amgen has consistently submitted broad evidence from relevant data sources including randomized clinical trials, to support the aforementioned position.[10,11,12] The most robust internally valid sources of data must be examined when making comparisons of the two products in cancer patients, because the clinical and demographic characteristics of patients being treated with Aranesp® and Procrit® have been found to be clinically and statistically significantly different to a large degree from each other. Thus, careful and detailed analyses must be performed to address substantial treatment selection bias and confounding by indication bias when anemia treatment is being delivered to patients undergoing chemotherapy.

Moreover, the duration of clinical benefit is different for the two products, as their administration schedule is different, and this fact must be taken into account when comparing use and costs of the two agents. We have previously submitted comprehensive clinical evidence to CMS from clinical trials and observational studies documenting comparable costs to achieve comparable clinical outcomes of the two products. Additionally, we have performed additional analyses using administrative claims data from various sources that are supportive of the findings from more robust sources of evidence. When appropriate analyses are performed using claims databases, we have observed that the dose conversion ratio ranges from 325 to 436 International Units (IUs) of Procrit® to 1 microgram of Aranesp®, with reimbursed amounts by payers being generally equivalent in cost per week.[13]

We provide a summary below of the two major studies that illustrate these findings; both have been presented at professional meetings and published in abstract form.

- Based on analyses of U.S. healthcare claims data, cancer patients treated with erythropoiesis-stimulating agents (ESAs) receive a weekly average of 40,398 units of Procrit® or 101 mcg of Aranesp® with a corresponding ratio of 431:1. These results are based on an episode-of-care methodology (including the duration of clinical benefit approach) to calculate average weekly does. The median time interval between ESA administrations supports the use of product specific duration of clinical benefit in an episode of care analysis. Therefore, comparisons of Aranesp® and Procrit® dosing should account for differences in duration of clinical benefit for these two agents.[14]

- Patterns of ESA use differ significantly between Aranesp® and Procrit®. The well established differences in pharmacokinetic profile between the drugs manifest as differences in dosing frequency in practice. Failure to properly account for duration of action can lead to substantially different and potentially misleading dose conversion ratios. In addition, because the administration schedule is different for the products, patients receiving Aranesp® may differ significantly in clinical characteristics compared to patients receiving Procrit®. Therefore, adjustments for patterns of use are necessary to appropriately compare the two drugs and their costs. When costs adjusted for the duration of clinical benefit were compared, the mean weekly cost of Aranesp® was lower than that for Procrit® ($560 for Aranesp® versus $645 for Procrit®).[15, 16]

While the studies discussed above underscore the importance of not drawing conclusions about drug utilization based solely on crude analyses of administrative claims data, evidence from such analyses can play a supportive role when considered in the context of more refined evidence such as data from randomized clinical trials or rigorous observational studies such as detailed chart reviews. Therefore, consistent with our past submissions, Appendix A includes an analysis conducted by the Moran Company of the most recently available OPPS claims data for 2006.

The Moran Company analyzed utilization of Aranesp® and Procrit® in the partial 2006 OPPS claims database released with the Proposed Rule. The analysis includes a summary the claims data limited to non-ESRD, oncology-only diagnoses.[17] This Medicare- and setting-specific claims analysis results in average doses entirely consistent with the dose conversion ratios discussed above. As was the case in prior submissions, the analysis conducted by the Moran Company continues to present doses that support a dose conversion ratio well above the dose conversion ratios that CMS chose to implement from 2003 through 2005. Assuming that the dose conversion ratio is calculated as the mean weekly dose of Procrit® in International Units (IUs) to that of Aranesp® in micrograms (mcgs) and assuming weekly administration of Procrit® and every-other-week administration of Aranesp®, the analysis by the Moran Company of Medicare claims data indicates a dose conversion ratio of 367 IUs of Procrit® to 1 mcg of Aranesp® (*i.e.*, 367:1)[18] Again, this dose conversion ratio is well above the figures previously used by CMS and, as such, reinforces the CMS proposal not to apply an "equitable adjustment" to Aranesp®.

When interpreting the analysis conducted by the Moran Company, it is important to recognize that due to the less frequent dosing nature of Aranesp®, Medicare and its

beneficiaries will pay less than or about the same for Aranesp® than for Procrit® at clinically comparable dosing and dosing regimens.

In summary, Amgen agrees with the agency's use of market-based pricing to reimburse for Aranesp® and other separately payable outpatient drugs.

As CMS prepares to finalize changes to OPPS for CY 2008, we recommend the following:

- Maintain market-based treatment of Aranesp® that has worked well for several years and continues to be the right policy;
- Continue to use the market-based ASP methodology to set payment rates for separately payable outpatient drugs; and
- Set reimbursement for separately payable drugs in the hospital outpatient setting at ASP + 6 percent.

* * * * *

Amgen appreciates this opportunity to provide important information and looks forward to working with you to ensure that Medicare beneficiaries treated in the hospital outpatient setting continue to have access to new and important biological therapies. Please contact Sarah Wells Kocsis by phone at (202) 585-9713 or by email at wellss@amgen.com to arrange a meeting or if you have any questions regarding our response. Thank you for your attention to this important matter.

Regards,

Joshua J. Ofman, MD, MSHS
Vice President,
Global Coverage and Reimbursement
and Global Health Economics

cc: Elizabeth Richter, Acting Director, Center for Medicare Management
Deborah Taylor, Acting Deputy Director, Center for Medicare Management
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Barry Straube, MD, Director, Office of Clinical Standards and Quality, Chief Medical Officer
Steve Phurrough, MD, Director, Coverage and Analysis Group

Attachment: Appendix A (Independent Analysis of 2006 OPPS Claims by the Moran Company)

REFERENCES AND NOTES

1 71 Fed. Reg. 42627-43129.

2 Aranesp® is indicated for the treatment of anemia in patients with non-myeloid malignancies where the anemia is due to the effect of concomitantly administered chemotherapy and for the treatment of anemia associated with chronic renal failure, including patients on dialysis and not on dialysis.

3 71 Fed. Reg. 68093; Fed. Reg. 68652.

4 As discussed at length in our comments on the 2008 Medicare Physician Fee Schedule Proposed Rule, Amgen is concerned that the proposed requirement to reallocate discounts among the drugs sold in "bundled arrangements" when calculating ASP would have the effect of distorting to some degree the accuracy of ASP as a measure of the average market price of specific products. See Amgen Inc., submission on the 2008 MPFS proposed rule, dated August 31, 2007.

5 Advisory Panel on Ambulatory Payment Classification (APC) Groups, Baltimore, MD: September 5-6, 2007

6 "Darbepoetin Alfa Briefing Document" prepared for the meeting between Amgen and CMS on April 28, 2003.

7 See Amgen Inc., submission on the 2005 OPPS proposed rule, dated October 7, 2004.

8 See Amgen Inc., submission on the 2006 OPPS proposed rule, dated September 15, 2005.

9 See Amgen Inc., submission on the 2007 OPPS proposed rule, dated October 6, 2006.

10 See Amgen Inc., submission on the 2005 OPPS proposed rule, dated October 7, 2004.

11 See Amgen Inc., submission on the 2006 OPPS proposed rule, dated September 15, 2005.

12 See Amgen Inc., submission on the 2007 OPPS proposed rule, dated October 6, 2006.

13 A dose conversion ratio can be calculated as a dose of Procrit® in International Units (IUs) to that of Aranesp® in micrograms (mcgs). For example, comparing 40,000 IUs of Procrit® and 100 mcgs of Aranesp® yields a dose conversion ratio of 400:1.

14 Berger A, Oster G. Use of Darbepoetin Alfa and Epoetin Alfa for Cancer-Related Anemia in Clinical Practice. *JMCP* 2007;13 (2): 203. Presented at AMCP, April, 2007.

15 Daniel G, Hurley D, Whyte JL, Grochulski WD, Willey V, Kallich JD. Analysis of Dose, Cost and Use Patterns of Erythropoiesis Stimulating Agents in Cancer Patients. ISPOR 12th Annual International Meeting; May 21-23. 2007; *Value in Health* 2007;10(3):134 PCN 34.

16 Daniel G, Hurley D, Whyte JL, Grochulski WD, Willey V, Kallich JD. Differences in Erythropoietin Stimulating Agent Dose and Use in Cancer Patients. Encore poster presented at MASCC June 2007. *Supportive Care in Cancer* 2007; 15 (6):758.

17 The Moran Company analysis is not adjusted for duration of clinical benefit. As such, the results from this analysis are presented in tandem with data from more robust analyses that take duration of clinical benefit into account.

18 This comparison assumes the provision of one administration service on the date that the product is delivered. Because actual services rendered depend on the needs of specific patients, patients may receive an administration service, an outpatient visit, either service, or some other combination of services on a particular date of service.

Appendix A:

Independent Analysis of 2006 OPPS Claims by The Moran Company

September 14, 2007

1655 N. FORT MYER DRIVE, SUITE 1250 ARLINGTON, VA 22209 (703) 465-9970 FAX (703) 465-9969

Memorandum (August 10, 2007)

TO: Chris Topeleski
Amgen

FROM: Rachel Feldman
The Moran Company

SUBJECT: 2005 and 2006 Outpatient Hospital Comparison of Utilization for Aranesp & Procrit

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Accompanying this memorandum is an analysis of the OPPS 2006 Claims file released with the 2008 proposed rule.

Detailed footnotes are included for each table. You will see an increase in claims from 2005 to 2006 even though the 2006 file understates what the actual 2006 volume will be when "run out" is included in the file released later this year. If you look back to the 2005 claims analysis based upon the data released with the 2007 proposed rule that we did for you last year, you can estimate how much difference there is likely to be between the 2006 proposed rule claims and the final numbers.

In making comparisons from one year to the next, note that drug codes changed for Aranesp and the drug unit also changed. Codes changed for Procrit as well, but unit definitions are consistent.

The Moran Company

Comparison of Aranesp and Procrit Claims & Oncology Utilization
Prepared for: Amgen
Sources: Medicare Hospital Outpatient Prospective Payment Claims Files
Released with Proposed 2008 Rule (2006 claims)
Date: August 10, 2007

Table 1 Summary of Arenesp and Procrit Claims: Non-ESRD Use Only[1]

		2006 claims (2008 proposed rule)**				
		Claims	Days	Lines	Units*	Units/ line
Aranesp†	Oncology Diagnoses[2]		176,411	176,453	42,433,390	240
	Oncology Dx with Chemotherapy Admin.[3] Same day with Aranesp		5,718	5,718	1,392,677	244
	All Diagnoses	278,785	344,460	344,564	63,772,669	185
Procrit‡	Oncology Diagnoses[2]		206,868	207,030	9,085,540	44
	Oncology Dx with Chemotherapy Admin.[3] Same day with Procrit		5,899	5,910	289,816	49
	All Diagnoses	358,232	540,154	540,534	16,890,400	31

[1] Excludes ESRD codes appearing in outpatient hospital claims

[2] ICD-9: 140-208, 230-239.9, V58.1, V58.0, 285.22

[3] 96400-96549.

† J0881 (1mcg unit)

‡ J0885 (per 1000 units) for 2006

* HCPCS unit definition varies by drug

** Note: the proposed file is cut based on claims filed, processed and paid by 12/31/2006. Therefore it understates real 2006 volume because claims that were not processed and paid for services delivered in 2006 by 12/31/2006 will not be included.

Table 2 Average Units Per Oncology[1] Line

	2006 claims (2008 proposed rule)		
	Lines	Units*	Units/ line
Aranesp†	176,453	42,433,390	240
Procrit‡	207,030	9,085,540	44

* HCPCS unit definition varies by drug

[1] ICD-9: 140-208, 230-239.9, V58.1, V58.0, 285.22

** Note: the proposed file is cut based on claims filed, processed and paid by 12/31/2006. Therefore it understates real 2006 volume because that were not processed and paid for services delivered in 2006 by 12/31/2006 will not be included. The 2006 final file includes all claims processed through several months of 2007.

† J0881 (1mcg unit) for 2006

‡ J0885 (per 1000 units) for 2006