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GlaxoSmithKline
Three Franklin Plaza
1600 Vine Street
Philadelphia, PA 19102

215 751 4000
www.gsk.com

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BY HAND DELIVERY AND ELECTRONIC MAIL
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Mr. Kerry N. 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, D.C. 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:

GlaxoSmithKline (GSK) appreciates the opportunity to comment on the proposed rule, dated August 2, 2007, entitled "*Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates*" (Proposed Rule).[1] GSK is a world-leading, research-based pharmaceutical company dedicated to improving the quality of human life by enabling people to do more, feel better, and live longer. The company is an industry leader, with significant products in several therapeutic areas, such as anti-infectives, HIV, central nervous system (CNS), respiratory, gastrointestinal, metabolic, cardiovascular, and oncology. We are pleased to submit our comments to the Centers for Medicare and Medicaid Services (CMS) to ensure Medicare beneficiaries continue to have access to our life-saving technologies.

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[1] 72 Fed. Reg. 42628 (August 2, 2007).

GSK understands the ongoing challenges CMS faces in advancing the healthcare system for Medicare beneficiaries so that they continue to receive high-quality services at an appropriate cost. While we generally support most of the efforts that CMS has proposed to promote fair drug reimbursement practices, we ask CMS to consider our comments regarding the proposed treatment of radiopharmaceuticals, particularly as applied to GSK's important Non-Hodgkin's Lymphoma (NHL) drug, BEXXAR®. The payment rate outlined in the Proposed Rule, if implemented, would result in a reimbursement rate that is more than 50 percent below the acquisition cost for the therapy. Consequently, Medicare beneficiary access to this important therapy would be severely impeded. It is already recognized that the BEXXAR® therapeutic regimen is currently under-utilized, with the current reimbursement environment cited as a major contributing factor.[2] The payment rates in the Proposed Rule would exacerbate this already critical situation by effectively making it difficult (if not impossible) for hospitals to offer this highly efficacious therapy to their NHL patients.

The causes for the underpayment of BEXXAR® under the approach in the Proposed Rule are two-fold:

1) the use of inadequate and inaccurate claims data by CMS to set reimbursement rates, and

2) the overall classification of the BEXXAR® Therapeutic Regimen by CMS does not properly reflect that the drugs composing the BEXXAR® radioimmunotherapeutic regimen are approved by the Food and Drug Administration (FDA) and meet the Medicare law definition of specified covered outpatient drugs (as has been recognized by CMS), and thus, must be paid on the basis of average acquisition cost or other statutorily specified methods discussed below.

In the sections that follow, we will summarize the statutory requirements with respect to payment for this radioimmunotherapeutic regimen; we will provide a detailed description of the regimen to ensure it is clearly understood and thus can be properly classified; and we will offer some suggestions about how best to achieve a legally supported and equitable payment result to address the disincentives in the current and proposed payment system so that this technology will be appropriately available to Medicare patients who need it. Proper treatment of, and payment for, this important regimen will be extremely important to ensure the availability of radioimmunotherapies for Medicare patients in the future.

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[2] Garber K. Journal of the National Cancer Institute. Vol 99. Issue 7. April 4, 2007 and The New York Times. July 14, 2007.

Overview and Summary of Recommendations

As described below, BEXXAR® is a comprehensive therapeutic regimen administered in multiple steps over the course of a two-week period. Although the Food and Drug Administration (FDA) has approved BEXXAR® as a single therapeutic regimen, the Proposed Rule purports to separate the regimen into multiple parts -- treating the radiolabeled dosimetric intervention as "diagnostic" and radioactive final intervention as therapeutic. Furthermore, CMS continues to misclassify the non-radiolabeled dose administered prior to the dosimetric radiolabeled and final radiolabeled intervention as a "supply," rather than as a single drug that is an intrinsic part of the FDA-approved therapeutic regimen.

The approach that CMS has proposed is neither clinically nor legally supported, will result in inadequate reimbursement to hospitals, and literally could result in patients not receiving this potentially life-saving treatment. GSK strongly urges CMS to modify its approach in the CY 2008 Final Rule. As described below, GSK recommends that CMS treat the full BEXXAR® therapeutic regimen (all four doses) as specified covered outpatient drugs, and that CMS establish a payment methodology based on actual, average acquisition costs for each and every drug component within the FDA-approved regimen.

As with other drugs and biologicals, payment could be based on the prevailing Average Sales Price (ASP)-based methodology for the BEXXAR® therapeutic regimen. In addition, the payments to hospitals should also include the costs incurred by hospitals for the compounding of the product by a radiopharmacy, a necessary step required to prepare the product for patient administration.[3] It is important to note that the compounding costs are service costs, and are provided by entities independent of GSK, including in a few instances, by hospital pharmacies that have specialized internal capability. Compounding costs are not GSK-incurred drug costs and would not be reflected within any ASP reports prepared by GSK.

Any of the suggested approaches would require modifications to the existing coding of the drugs in the BEXXAR® therapeutic regimen, and would also differ significantly from the policies proposed by CMS for reasons we believe are supported clinically and in law. The following sections will describe the regimen in detail, illustrate the problem areas that we respectfully request that CMS address, and provide some suggestions for how CMS might better proceed to achieve an equitable recognition of this therapy within the OPPS legal and policy framework.

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[3] The Medicare statute directs that overhead and related expenses, such as pharmacy and handling costs, should be factored into the ambulatory payment classifications for specified covered outpatient drugs. SSA § 1833(t)(14)(E).

For general reference purposes, we have provided a table outlining payment history for the BEXXAR® therapeutic regimen in the hospital outpatient setting.

HCPCS Code	Description	CY 2005 Payment Rate (Final)	CY 2006 Payment Rate (Final)	CY 2007 Payment Rate (Final)	CY 2008 Payment Rate (Proposed)
G3001*	Supply and administration of tositumomab, 450 mg	$2,250.00	$2,250.00	$1,374.83	$1,925.11
G3001*	Supply and administration of tositumomab, 450 mg	$2,250.00	$2,250.00	$1,374.83	$1,925.11
A9544***	I131 tositumomab, dx	$2,241.00	Cost-Based**	Cost-Based**	No separate payment
A9545***	I131 tositumomab, tx	$19,422.00	Cost-Based**	Cost-Based**	$8,283.41
	TOTAL	$26,163.00	$4,500.00 + Cost-Based**	$2,749.66 + Cost-Based**	$12,133.63

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

Proper Payment For BEXXAR® Should Treat the Drugs Comprising the Therapeutic Regimen as Specified Covered Outpatient Drugs

CMS has correctly noted on several occasions since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), that the BEXXAR® therapeutic regimen is a "specified covered outpatient drug" (SCOD) as that term is defined in § 1833(t)(14)(B)(i) of the Social Security Act (SSA). For example, in 2004, CMS concluded that, "Zevalin and Bexxar are radiopharmaceuticals, and the MMA includes them as 'specified covered outpatient drugs' for OPPS payment purposes."[4] Most recently, in the preamble to the CY 2008 HOPPS Proposed Rule, CMS confirmed that: "In accordance with section 1833(t)(14)(B)(i)(I) of the Act, radiopharmaceuticals are classified under the OPPS as SCODs."[5]

[4] 69 Fed. Reg. 65682, 65787.

[5] 72 Fed. Reg. 42628, 42737.

Medicare Statutory Payment Options--The Medicare statute directs that CMS must pay for SCODs at either the "average acquisition cost for the drug for that year" *or* "if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." These citations reference the ASP+6 percent, special AWP-based reimbursement rates, or the Part B Competitive Acquisition Program (CAP) payment rate approaches.[6] Therefore, the Medicare statute mandates that SCODs must be paid according to one of these alternative payment methods and under the circumstances presented does not authorize CMS to substitute hospital charges or other proxies for the payment options specified in the statute, including for hospital acquisition costs.

Nevertheless, for therapeutic radiopharmaceuticals, CMS is now "proposing to establish CY 2008 payment rates based on their mean units costs from our CY 2006 OPPS claims data."[7] Although CMS acknowledges in the Proposed Rule that "section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs be set prospectively based on a measure of average acquisition cost," CMS "believe[s] [its] claims data offer an acceptable proxy for average hospital acquisition cost and associated handling and preparation costs for radiopharmaceuticals."[8] GSK respectfully disagrees. Prospective payment based on historical hospital claims data is not, in our view, appropriate for therapeutic radioimmunotherapies because it is not consistent with the statutory requirement discussed above and the data chosen by CMS do not serve as an accurate measure of the average hospital acquisition and associated handling cost of separately payable radioimmunotherapy regimen products. Further, § 1833(t)(14)(D)(ii)-(iv) of the Act also clearly anticipates that the Secretary (authority delegated to CMS) would carry out ongoing and statistically valid surveys of hospitals' actual acquisition costs in order to establish appropriate payment levels, under this payment option. The statute does not contemplate failure to carry out this data collection requirement and substituting a proxy for average acquisition cost. To our knowledge, no government entity has conducted a survey of hospitals' actual acquisition costs for the BEXXAR® therapeutic regimen for Medicare payment purposes. CMS has indicated that such surveys are burdensome for the Agency, hospitals, and/or manufacturers. Therefore, we suggest that CMS consider our recommendation to adopt one of the other options permitted in this setting, namely the ASP approach, which would rectify these issues.

Separately, as CMS has acknowledged, charge compression issues in how hospital cost-to-charge ratios are calculated for payment purposes can result in an underestimation of costs for high-cost radiopharmaceuticals (and hence an

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6 SSA § 1833(t)(14)(A)(iii).

7 Id. at 42738.

8 Id.

inadequate payment rate). CMS in fact confirms in the Proposed Rule that it "received anecdotal reports from some industry stakeholders asserting that the mean costs for the most expensive radiopharmaceuticals are understated in our claims data."[9] For this reason, among others described in this letter, the data that CMS proposes to use result in payment rates that amount to only half of the BEXXAR® acquisition cost.

ASP Payment Alternative--As discussed above, § 1833(t)(14)(A)(3) of the Act specifies an alternative to acquisition cost in the event that adequate information is unavailable -- the ASP methodology. Although GSK believes that CMS should rely upon data that reflect the actual acquisition cost of radiopharmaceuticals to hospitals in setting payment rates (and not poor proxies), an appropriate and statutorily supported alternative approach would be the ASP-based methodology that is used for drugs and biologicals reimbursed under Medicare Part B. Although GSK is not required, and therefore, currently does not report ASPs for the drugs comprising the BEXXAR® therapeutic regimen, GSK intends to submit 2Q 2007 ASPs to CMS and would initiate routine, quarterly ASP reporting promptly if CMS were to adopt this approach in the Final Rule. This approach would be consistent with the approach that CMS proposed for CY 2006[10] and would be within CMS's authority for radioimmunotherapies.[11] We note that in CMS's referenced discussions in the 2006 rulemaking process, that CMS stated in part:

> "As we do not have ASPs for radiopharmaceuticals that best represent market prices, we are proposing as a temporary 1-year policy for CY 2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital's charge for each radiopharmaceutical agent adjusted to cost...Section 303(h) of Pub. L. 108–173 exempted radiopharmaceuticals from ASP pricing in the physician office setting where the fewer numbers (relative to the hospital outpatient setting) of radio-pharmaceuticals are priced locally by Medicare contractors. However, radiopharmaceuticals are subject to ASP reporting. We currently do not require reporting for radiopharmaceuticals because we do not pay for any of the radiopharmaceuticals using the ASP methodology. However, for CY 2006, we are proposing to begin collecting ASP data on all radiopharmaceutical agents

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9 72 Fed. Reg. 42740 (August 2, 2007).

10 70 Fed. Reg. 42674, 42727-28 (July 25, 2005).

11 MMA, § 303(h); *see also*, 70 Fed. Reg. 42674, 42727 ("radiopharmaceuticals are subject to ASP reporting").

for purposes of ASP-based payment of radiopharmaceuticals beginning in CY 2007."[12]

Although CMS ultimately decided to postpone adoption of the ASP method, GSK notes that CMS has been receptive to this option, such thinking could be applied to radioimmunotherapies (all drugs in the regimen), and it presents many advantages by bringing those drugs properly into the framework of other SCODs in the outpatient hospital setting.

Finally, in addition to the payment for the BEXXAR® therapeutic regimen, hospital payments also must include the costs incurred for the compounding of the product by a radiopharmacy, a necessary step required to prepare the product for patient administration.[13] This cost is independent of the drug costs charged by GSK for the four components of the BEXXAR® therapeutic regimen. Following is detailed information on the regimen itself.

Non-Hodgkin's Lymphoma and the BEXXAR® Therapeutic Regimen

Each year, about 54,000 Americans are diagnosed with NHL.[14] The National Cancer Institute (NCI) estimates that, in 2007 alone, there will be 63,190 new cases of NHL and that 18,660 people will die from this disease. Although NHL can occur at any age, most people with this disease are older than age 60.[15]

Our NHL product, BEXXAR® (tositumomab and Iodine I 131 tositumomab), differs from conventional chemotherapy in that the entire treatment takes place over seven to fourteen days, and is approved by the FDA as a single, one-time therapeutic intervention, as opposed to the multiple cycles of therapy required when a patient receives chemotherapy. The BEXXAR® therapeutic regimen is a second-line therapy used for those patients for whom first-line therapies have not achieved a good clinical outcome. The disease course of follicular/low grade NHL is such that patients do initially respond (i.e., their tumors shrink) to chemotherapy. However, their disease invariably returns and they will then need to receive additional treatment. Many patients treated with the BEXXAR® therapeutic regimen have experienced disease remissions that have lasted several years with a single one time intervention that is complete within 7 to 14 days. More patients experience these types of disease remissions when BEXXAR® is used early in the course of their disease.

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12 70 Fed. Reg. 42727 (July 25, 2005).

13 SSA, § 1833(t)(14)(E).

14 Non-Hodgkin's Lymphoma, National Institutes of Health (NIH) Publication No. 05-1567.

15 Id.

The BEXXAR® therapeutic regimen consists of four different drug doses, each described with a unique National Drug Code (NDC) number (thus demonstrating their status as drugs), as follows:

1) a dosimetric dose of tositumomab (NDC 00007-3260-31),

2) a dosimetric dose of Iodine I-131 tositumomab (NDC 00007-3261-01),

3) a therapeutic dose of tositumomab (NDC 00007-3260-36), and

4) a therapeutic dose of Iodine I-131 tositumomab (NDC 00007-3262-01).

CMS has consistently treated dose numbers 1 and 3 above incorrectly as medical supplies, rather than as separate drugs, even though they have their own unique NDCs. CMS also proposes to treat the radioactive dose described in number 2 above as a "diagnostic" to be packaged. This dose, in fact, is not diagnostic, but rather, together with dose number 1 above, represents the initiation of the radioimmunotherapeutic regimen. Prior to receiving BEXXAR®, the patient already has been diagnosed with NHL and has failed some type of treatment (i.e., conventional chemotherapy, or combined immunochemotherapy). In short, each drug is part of the therapeutic intervention, and the drug dosing in this regimen should not be confused with numerous other radiopharmaceutical products that serve diagnostic purposes in medical care. Because proper coding and payment depends on fully understanding the BEXXAR® therapeutic regimen, we have outlined the infusion process below in some detail.

Step 1: <u>Dosimetric Dosing</u>

The non-radioactive monoclonal antibody (tositumomab), hereinafter referred to as the "dosimetric cold" dose, is administered initially to the patient. This infusion helps prepare the previously-diagnosed NHL patient, who has failed conventional chemotherapy, or combined immunochemotherapy, to receive a subsequent radioactive component. This cold dose is administered to ensure that the radioactive dose is directed towards the tumor cells and not areas where normal B-cells reside, e.g., the liver. After administration of the "dosimetric cold" dose, the same monoclonal antibody is administered with a trace amount of radioactive isotope (Iodine I 131 tositumomab) attached. This radiolabeled monoclonal antibody is referred to as the "dosimetric warm" dose.

The purpose of the dosimetric step, both the "cold" dose and the "warm" dose, is to both initiate therapy and to enable physicians to administer the appropriate *total* amount of radiolabeled monoclonal antibody specific to an individual patient's needs to achieve the prescribed necessary dose of radiation. After the "dosimetric warm" dose is administered, three total-body scans are performed over the course of several days. In effect, therapy has begun with the administration of these doses, but is not completed until information from the scans permit calculation of the specific *final* amount of the radioactive product to include in the patient-specific *final* therapeutic dose under the BEXXAR®

therapeutic regimen. The amount of radioactivity required for the prescribed total-body dose over the complete course of the BEXXAR® therapeutic regimen is variable across patients, and is dependent upon the assessment of each patient's reaction to the dosimetric steps in the regimen.

Step 2: Final Dosing

After completion of the dosimetric steps, the "cold" dose is again administered. This infusion helps prepare the patient to receive the subsequent radioactive dose. Next, a "hot" dose, containing the patient-specific *final* amount of radiolabeled monoclonal antibody, is administered, thus completing the regimen. The BEXXAR® therapeutic regimen involves infusion of all four of the separate drug components to provide the single course of therapy to the patient.

For example, a typical regimen may be outlined as:

Day 0: A 450 mg "dosimetric cold" dose is administered intravenously (IV) to a patient over a 60 minute period, followed by a "dosimetric warm" dose (5mCi) over a 20 minute period. The first of three total-body scans is performed on the patient for determination of the appropriate total-body dose of radiation for utmost effectiveness through dosimetry following the third scan.

Day 2, 3, or 4: The second of three total-body scans is performed on the patient for determination of the appropriate total-body dose of radiation for utmost effectiveness through dosimetry following the third scan.

Day 6-7: The third of three total-body scans is performed on the patient and the dosimetry is calculated separately to determine appropriate total-body dose of radiation for utmost effectiveness.

Day 7 (or any subsequent day up to Day 14): A 450 mg "cold" dose is administered, followed by an intravenous infusion of the "hot" dose—the specific amount unique to each patient based on reactions to and data from the "dosimetric warm" dose, administered on Day 0.

* * * *

As described below, GSK believes that the payment rules for BEXXAR® should be corrected in a number of respects to ensure that hospitals are reimbursed for their true average acquisition costs for the entire BEXXAR® therapeutic regimen.

The Proposed HOPPS Payment Methodology Misclassifies Integral Drug Components of the BEXXAR® Therapeutic Regimen as Diagnostic

CMS has proposed a payment methodology that treats the various components of the BEXXAR® therapeutic regimen differently, thus understating the total payment amount to hospitals that administer it, relative to their acquisition

costs. Currently, two of the components, tositumomab dosimetric and tositumomab therapeutic (referred to above as the two "cold" doses--numbers 1 and 3 above) are incorrectly classified as supplies and assigned a temporary G-code (G3001), while the other two radiolabeled components (referred to as the "warm" and "hot" doses, respectively--numbers 2 and 4 above) are assigned A-codes (A9544 and A9545, respectively). The "cold" doses should be classified as drugs, assigned J-codes, and paid as such. This is addressed further in the next section. In addition, CMS has proposed to treat the radiolabeled drug administered in the dosimetric step in the regimen, the "dosimetric warm" dose (number 2 above), as "diagnostic" and subject to packaging into the associated procedure payment.

Under the BEXXAR® therapeutic regimen, however, the "dosimetric warm" dose and subsequent patient evaluation are not diagnostic. Instead, they are an integral part of the FDA-approved BEXXAR® therapeutic regimen; they represent the initiation of therapy, not diagnosis of disease, and lead to a determination of the amount of radiolabeled monoclonal antibody required for the final therapeutic dose – the "hot" dose. The "hot" dose is patient-specific and administered subsequent to the dosimetry and evaluation of the biodistribution of the initial "dosimetric warm" dose in the patient, using three total-body scans to ensure that, in the aggregate, the patient receives the total-body dose of radiation demonstrated as efficacious. This unique radioimmunotherapeutic regimen is distinct from the broader class of radiopharmaceuticals, which are generally used for medical diagnostic purposes. The primary purpose of every component and step of the BEXXAR® therapeutic regimen is therapeutic, not diagnostic. Indeed, patients who receive the initial "dosimetric cold" and "dosimetric warm" doses have already been diagnosed with NHL, and have relapsed or failed prior treatment regimen(s).

While we understand the CMS intent to encourage efficiency in the outpatient setting, incorrectly packaging the "dosimetric warm" dose with the patient evaluation would not promote hospital efficiencies by selecting the most clinically appropriate diagnostic approach as described in the Proposed Rule. In the case of the BEXXAR® therapeutic regimen, it would be clinically inappropriate and infeasible to use any other agent. As explained above, the purpose of dosimetric I-131 tositumomab is to allow physicians the ability to administer the appropriate amount of radioactivity specific to an individual patient's needs to achieve the prescribed total body dose of radiation. The amount of radioactivity needed to be administered in the final "hot" dose, in order to gain the therapeutic effect of the product without being exposed to unnecessary radiation, is calculated based on the characteristics and clinical responses of each specific patient to the "dosimetric warm" dose. This can only be accomplished in a clinically appropriate manner if I-131 tositumomab, specifically, is administered to the patient. Therefore, hospitals cannot select another substitute for dosimetric I-131 tositumomab.

The Cold Doses Are Misclassified as Supplies When They Are In Fact Drugs

CMS repeatedly has asserted in the Proposed Rule that it considers "unlabeled tositumomab"[16] (i.e., the "cold" doses) as a supply and not as a drug or biological, stating "unlabeled tositumomab is not approved as either a drug or a radiopharmacetical, but is a supply that is required as part of the Bexxar treatment regimen."[17] Contrary to CMS's proposal, however, the FDA has approved these drugs as part of the therapeutic regimen, and these doses are also recognized as drugs in approved compendia listings.

For example, in the June 2003 letter approving BEXXAR®, the FDA noted that:

> "Tositumomab and Iodine I 131 Tositumomab, administered as a therapeutic regimen, are indicated for the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following [conventional] chemotherapy (emphasis added)."[18]

Similarly, the **DESCRIPTION** section of the BEXXAR® FDA label provides:

> "The **BEXXAR** therapeutic regimen (Tositumomab and Iodine I 131 Tositumomab) is an anti-neoplastic radioimmunotherapeutic monoclonal antibody-based regimen composed of the monoclonal antibody, Tositumomab, and the radiolabeled monoclonal antibody, Iodine I 131 Tositumomab (emphasis added)."[19]

The FDA label confirms that the "cold" doses are part of the approved regimen and thus are drugs and not supplies.

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[16] Characterization of the "cold dose" as "unlabeled" refers to the fact that it is not associated with a radioactive isotope (i.e., it is not radioactive). This term should not be misconstrued as meaning the cold doses are not within labeling or otherwise not approved by the FDA for the stated uses - the cold doses are included in the FDA-approved label for the BEXXAR® therapeutic regimen.

[17] See 68 Fed. Reg. 63443 (2003); See 70 Fed. Reg. 68654 (2005); See 71 Fed. Reg. 68034 (2006).

[18] This FDA letter may be found at: http://www.fda.gov/cder/foi/appletter/2003/tosicor062703L.htm (accessed August 29, 2007).

[19] This FDA label may be found at: http://www.fda.gov/cder/foi/label/2004/125011_0024lbl.pdf (accessed August 31, 2007).

The Medicare statute and related sub-regulatory guidance compel the same conclusion. For instance, SSA § 1861(t)(1) defines drugs and biologicals as follows:

> The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.[20]

The Medicare Benefit Policy Manual similarly provides:

> Drugs or biologicals must be determined to meet the statutory definition. Under the statute § 1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USP-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. . . Inclusion in such a reference . . . is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above compendia.[21]

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[20] SSA § 1861(t)(1).

[21] Medicare Benefit Policy Manual, Chapter 15, § 50.1 Definition of Drug or Biological.

The heading of the USP-DI BEXXAR® listing is: "Tositumomab and I 131 Tositumomab." In fact, this description is used throughout the USP-DI listing for BEXXAR®. The BEXXAR® therapeutic regimen thus consists of the two cold doses, and the warm and hot doses. All of these doses -- "cold," "warm," and "hot" -- are encompassed in the Medicare definition of drugs as a combination drug (Section 50.1 of Chapter 15 of the Medicare Benefit Policy Manual, quoted above) because "the combination itself or all of the therapeutic ingredients of the combination are included . . . in [the USP-DI]." Because the FDA approved tositumomab as one of the drugs in the BEXXAR® therapeutic regimen and because that regimen is included in the USP-DI, BEXXAR® is a drug under the definition in the Medicare statute. Furthermore, the BEXXAR® therapeutic regimen cannot be administered without the cold doses. Indeed, the therapy cannot be delivered without any of the individual components that comprise the therapeutic regimen. For these reasons, we urge CMS to recognize the cold dose as a drug for payment purposes and all of the doses should be coded accordingly.

Recommendations

To ensure that patients have appropriate access to the BEXXAR® therapeutic regimen and to satisfy the statutory requirement that payment rates for these products be measured by average acquisition cost, GSK recommends that CMS consider the approach described below to ensure adequate payment for a course of the BEXXAR® therapeutic regimen:

1. Recognize tositumomab (the two "cold" doses) as a drug by creating a J-code for it and setting a payment rate using ASP or another recognized measure of average acquisition cost.

2. As addressed above, because both doses of tositumomab have their own NDC numbers and the FDA has recognized these doses as part of the approved BEXXAR® regimen, tositumomab should be paid separately as a drug. The administration of the two separate doses of tositumomab should be allowed for the two 60 minute infusions (according to the dosing schedule outlined from the Prescribing Information in Attachment A), according to usual practice.

3. An alternative to actions 1 and 2 above would be to retain the G3001 code for the cold doses but to set the payment rate for those drugs equal to ASP+6 percent (or another recognized measure of acquisition cost) for tositumomab plus the payment rate for a 60 minute infusion of tositumomab, according to usual practice.

4. CMS should not separate the component parts of the BEXXAR® therapeutic regimen by isolating the "dosimetric warm" dose from the therapeutic regimen and treating it as a diagnostic procedure for payment purposes.

5. CMS should use ASP data to set the payment rates for dosimetric I-131 tositumomab (A9544) and therapeutic I-131 tositumomab (A9545) (the "warm" and "hot" doses, respectively).

6. CMS should include the radiopharmacy compounding cost in the payment rates for the drugs or create new G codes for reporting these costs.

Consideration of Composite APC for the BEXXAR® Therapeutic Regimen

GSK recommends that CMS exercise caution if considering the BEXXAR® therapeutic regimen as a candidate for a Composite APC. For a variety of circumstances, a small percentage of patients do not receive all of the four drug components in the BEXXAR® therapeutic regimen. Therefore, a composite APC could inappropriately result in overpayment by CMS, in some cases.

However, if CMS proceeds with such an evaluation, there are a number of components that we believe CMS would need to properly identify, evaluate, and value for potential inclusion in such an APC, which we provide in Attachment B. Most importantly, the drug product coding, classification and payment issues must be addressed prior to moving forward on an even more complex proposal layering in other services and costs. Further, CMS would need to address the "multi-episode" aspect of the BEXXAR® regimen, as services and products are administered over approximately a 7-14 day period in the hospital outpatient setting. This presents numerous hospital billing challenges that would need to be addressed at a Medicare operational level before such a concept could proceed.

Due to the complexities touched on above, if CMS were to propose a composite APC affecting radioimmunotherapy regimens, we strongly recommend that CMS publish in the OPPS Notice of Proposed Rulemaking in 2008 or 2009, any such proposed methodology. This will provide affected hospitals, physicians, and other stakeholders an opportunity to evaluate and publicly comment upon the specific elements and impact of the proposal, consistent with the purposes and requirements of the Administrative Procedures Act.

If such changes were developed and implemented, we recommend they be accompanied by a robust educational program for hospitals regarding proper billing and coding.

Conclusion

Radioimmunotherapeutic regimens are relatively new and developing therapeutic interventions. Medicare payment policy will have a material impact upon the future availability of this important technology. Appropriate recognition in payment systems of the unique labeling and structure of these interventions is essential to ensure the availability of this highly complex, but efficacious technology. Evidence suggests this therapy is being used by only a small number

of patients for whom it is indicated and beneficial, with a major cause being the current reimbursement environment. Proper recognition and valuation of the components of the first regimens of this scientific platform to enter into patient care will permit hospitals to offer these regimens to patients who can truly benefit from these innovative therapies, without reimbursement rates negatively impacting their ability to deliver and offer these therapies. In addition, it will create an appropriate precedent for future radioimmunotherapeutic regimens that that FDA may approve.

We acknowledge that this is an unusual circumstance and thank you for your thoughtful and close attention to this matter to ensure that the healthcare needs of Medicare beneficiaries are properly met. If you have any questions, or would like to discuss this matter in further detail, please contact Roger Hunter at 215-751-7470 or roger.a.hunter@gsk.com.

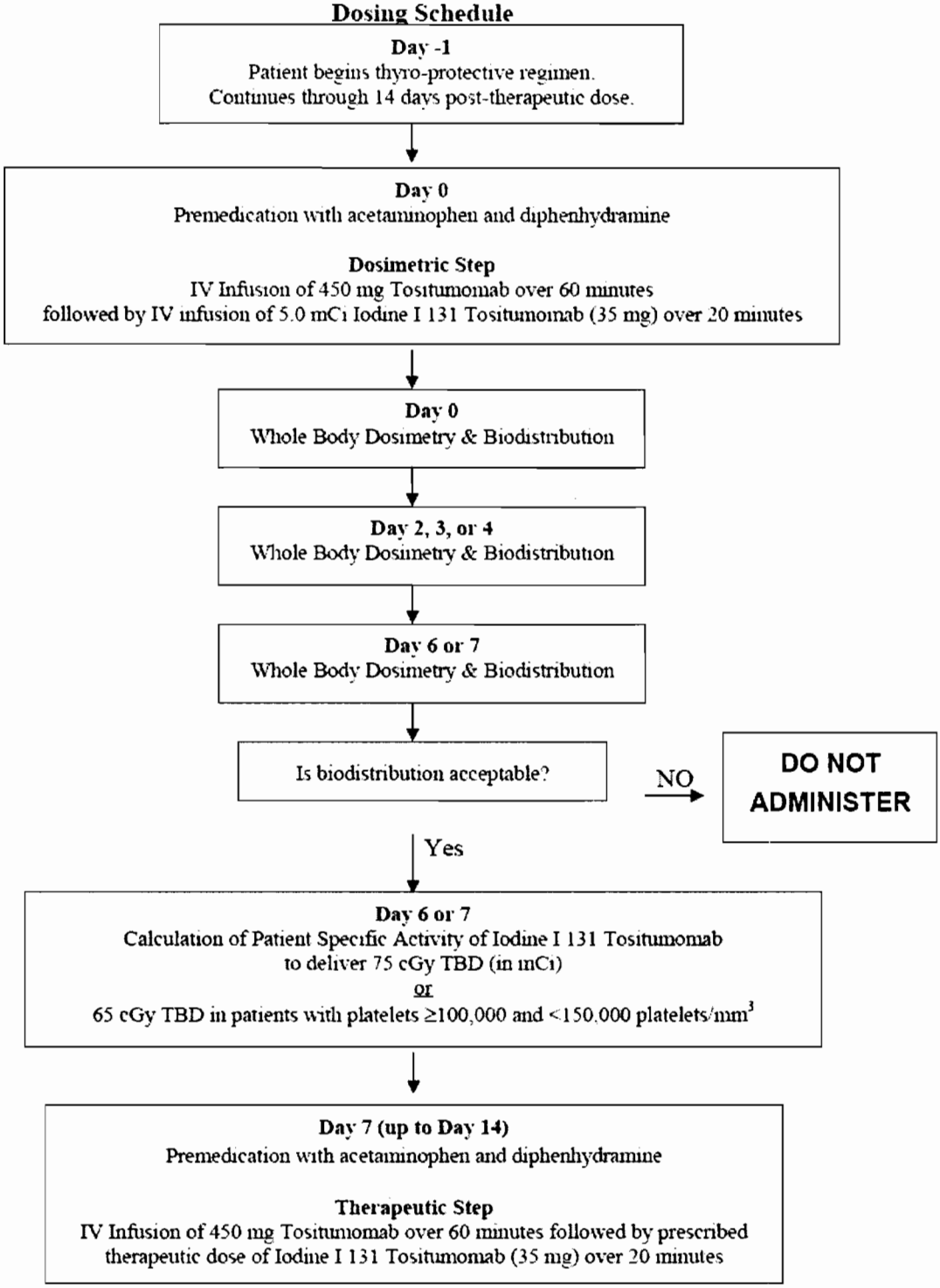
Respectfully submitted,

Roger A. Hunter
Executive Director
New Product Planning and Policy
GlaxoSmithKline Oncology/Critical & Supportive Care

ATTACHMENT A
Dosing Schedule (Figure 1) from BEXXAR® Prescribing Information

Figure 1

Dosing Schedule



ATTACHMENT B

Code	Descriptor	Basis for Rate-Setting
New Service/ New Code	Tositumomab for Dosimetric Step (NDC 00007-3260-31)	ASP (or WAC): update quarterly
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug (Infusion for tositumomab prior to A9544)	Median costs from claims data and update annually
A9544	Iodine I-131 tositumomab, diagnostic, per study dose (NDC 00007-3261-01)	ASP (or WAC): update quarterly
79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion (administration of A9544)	Median costs from claims data and update annually
78804	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging.	Median costs from claims data and update annually
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician	Median costs from claims data and update annually
New Service/ New Code	Tositumomab for Therapeutic Step (NDC 00007-3260-36)	ASP (or WAC): update quarterly
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug (Infusion for tositumomab prior to A9545)	Median costs from claims data and update annually
A9545	Iodine I-131 tositumomab, therapeutic, per treatment dose (NDC 00007-3262-01)	ASP (or WAC): update quarterly
79403	Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion (administration of A9545)	Median costs from claims data and update annually
New Service/ New Code	Radiopharmacy Compounding Fee for A9544 and A9545	Hospital invoices
Numerous	All other packaged items and services	Median costs from claims data and update annually

THE AMERICAN SOCIETY OF HEMATOLOGY
1900 M Street, NW, Suite 200, Washington, DC 20036 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

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September 11, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS 1392-P, Proposed Changes to the Hospital Prospective Payment System and CY 2008 Rates

Dear Mr. Weems:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2008. ASH represents approximately 11,000 hematologists in the United States who are committed to the treatment of patients with blood-related disorders. ASH members include hematologists and hematologist/oncologists who provide expert care to Medicare beneficiaries and whose services are frequently covered by the Hospital Outpatient Prospective Payment System (HOPPS). ASH would like to offer specific comments on issues that affect hematologists.

Bone Marrow and Stem Cell Processing Services

ASH is concerned about the APC assignment and the proposed payment level for the bone marrow and stem cell processing procedures, Codes 38207-38215. These services involve the expert processing of bone marrow and stem cells prior to transplantation and include such critical procedures as the therapeutic removal from the graft of certain undesirable cells. Since the inception of the HOPPS program, and until the present time, CMS has failed to recognize and appropriately fund these important CPT codes.

CMS established three "G" codes with which to report these services. Two of the codes were erroneously classified as clinical diagnostic laboratory tests and excluded from HOPPS: G0265 (cryopreservation, freezing and storage of cells for therapeutic use) and G0266 (thawing and expansion of frozen cells for therapeutic use). The third code, G0267 [bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (e.g., T-cells, metatastic carcinoma)], was covered under HOPPS.

ASH appreciates the fact that, after several years of discussion, codes 38207-38215 will now be recognized under HOPPS according to the proposed rule, but we are concerned about their proposed APC assignment. Codes 38207-38209 were assigned to APC 0344, Level IV Pathology, with a proposed payment rate of $54.69. This APC consists primarily of anatomic pathology services, including Codes 88307 and 88309, that involve the handling and preparation of tissue specimens for microscopic evaluation. Clearly, the effort, processes and, therefore, the costs involved in cryopreserving,

thawing and washing bone marrow/stem cells for a potentially life-saving transplant are very different from the costs involved in preparing tissue for diagnostic studies.

ASH, working with AABB, ASBMT and other interested societies, conducted a survey of hospital centers that perform bone marrow transplantation services including some where these highly specialized processing services are performed. We requested data from the centers on direct costs: clinical labor, supplies and reagents. Based on the data we received from seven institutions, the mean and median direct costs of performing these services are as follows:

Code 38207, Cryopreservation and storage – mean $809 and median $500
Code 38208, Thawing without washing – mean $206 and median $144
Code 38209, Thawing with washing – mean $325 and median $206

Assuming direct costs are about 50 percent of total costs; this would indicate that total costs approximate twice the direct cost estimates. This would raise the estimate of total costs to:

Code 38207, Cryopreservation and storage – mean $1,618 and median $1,000
Code 38208, Thawing without washing – mean $412 and median $288
Code 38209, Thawing with washing – mean $650 and median $412

ASH recognizes that eventual reporting under this series of codes will ultimately provide CMS with charge and cost data for these codes. However, at a minimum, these data will not be available until the payment rates are established for CY 2010 based on CY 2008 claims. In the interim, ASH urges CMS to place these codes in an APC that pays substantially more than the $54 amount which will cover only a small fraction of the real costs. ASH suggests that APC 0111, Blood Product Exchange (paying $776) would be an appropriate initial payment level. It would pay substantially less than the costs of freezing and storing the product and somewhat more than the cost of thawing the same material. On average, this APC would be a reasonable interim APC until better data are available in two years.

G0267, currently paid for under HOPPS, is assigned to APC 0110. This is the blood transfusion APC which has a payment rate of $222.44. The data in this APC is dominated by transfusion procedures particularly Code 36430. The median cost data for G0267 indicate only 194 single claims were billed (438 total claims) with a median cost of $405.84. ASH is confident that most of the billings within G0267 are for the lower cost services such as red blood cell removal (Code 38212). On the other hand, codes 38210 (T-cell depletion) and 38211 (tumor cell depletion) are extremely costly services that are performed by only a limited number of facilities and very rarely in the Medicare age group. We have data for five facilities that indicate that the reagent kits alone for codes 38210 and 38211 cost from $5,913 to $7,968 per patient and clinical staff costs range from $270 to $1,344. Thus, the $222 payment rate would cover only a miniscule portion of the costs. ASH, therefore, would like two options for pricing Codes 38210 and 38211:

Option 1—Place Code 38210 and Code 38211 into a higher paying APC. ASH suggests APC 0112, Apheresis and Stem Cell Procedures, with a payment rate of $2.035.93. We think this would be a reasonable interim rate until adequate cost data is collected.

Option 2—Reimburse Code 38210 and Code 38211 on a cost-based method based on a hospital's charges reduced to cost using the cost to charge (CCR) methodology. This would be analogous to the method used for pricing pass-through devices and would also be an appropriate interim measure until data is available for these processing services.

Regarding the other cell depletion codes, 38212-38215, the Society notes that survey data for seven hospitals indicated the following direct costs (clinical labor and supplies) for these codes:

Code 38212, Red Blood Cell Removal—Mean $591 and Median $239
Code 38213, Platelet Depletion—Mean $272 and Median $272
Code 38214, Plasma (Volume) Depletion—Mean $269 and Median $124
Code 38215, Cell Concentration in Plasma—Mean $265 and Median $265

Assuming direct costs are approximately half of total costs, this would result in the following estimates of total costs:

Code 38212, Red Blood Cell Removal—Mean $1,082 and Median $478
Code 38213, Platelet Depletion—Mean $544 and Median $544
Code 38214, Plasma (Volume) Depletion—Mean $538 and Median $248
Code 38215, Cell Concentration in Plasma—Mean $530 and Median $530

In lieu of APC 110, we would recommend that Codes 38212-38215 be placed in a separate APC using the actual median cost data for G0267. This would raise the payment level to the $400 level from the proposed $220 rate of APC 0110. This change is clearly supported by the survey data. When CMS has adequate claims data for the individual codes it might be appropriate to adjust the APC grouping further. However, it is an appropriate and reasonable interim step.

Payment for Radioimmunotherapy Agents

ASH is extremely concerned about the proposed payment rate for Bexxar (I131 Tositumomab), which is a radioimmunotherapy (RIT) agent. Similar issues apply to Zevalin (Ibritumomab Tiuxetan), which is also a RIT. The principle use of a RIT is for the treatment of non-Hodgkin's Lymphoma for patients who have not responded well to a prior course of chemotherapy treatment. There are two major problems with the proposed payment for I131-Tositumomab. First, the initial treatment is considered as a diagnostic procedure. Under the proposed rule, the cost of radiopharmaceuticals for diagnostic as opposed to therapeutic purposes will be "packaged" and not separately paid. Second, the proposed payment level for I131-Tositumomab grossly underestimates the cost of this product.

The complete I131-Tositumomab treatment regimen is provided over 7 to14 days. After an initial treatment, the patient is evaluated through whole body dosimetry to determine if the biodistribution of the agent is acceptable. If it is not, no further I131-Tositumomab treatment is provided. In the proposed rule, CMS indicates its intention to discontinue separate payment for diagnostic radiopharmaceuticals and to package the cost of the agent in the cost of the nuclear medicine procedure. CMS classified the initial dose of I131 Tositumomab as a "diagnostic" so that it would be classified as packaged and given "N" status under HOPPS. This decision is erroneous. All the doses of I131-Tositumomab are intended to be therapeutic and part of a multi-day treatment regimen and thus paid separately. This is the case even if the decision is made not to furnish any further doses because the biodistribution of the initial dose of the agent was not considered acceptable.

It is also our understanding that the proposed payment rate for the therapeutic use of I131-Tositumomab would cover less than half of the $30,000 cost to hospitals. It is clear that the CMS' estimate of costs grossly undervalues actual costs of I131-Tositumomab. Whether this is because of a defect in the cost to charge method (CCR) due to the unwillingness of hospitals to adequately mark up the charges for very costly services (i.e., the phenomenon of charge compression) or for other reasons, unless corrected, this could prove devastating to this important therapy. It may severely limit patient access to this invaluable treatment since hospitals will not be able to absorb a loss exceeding $16,000 per patient. If this occurs it will eliminate one of the few treatment options and perhaps the only treatment option for some patients with non-Hodgkin's Lymphoma who have failed chemotherapy treatment. And, finally, it could have a chilling effect on the development of future drugs and radiopharmaceuticals for treating other forms of cancer and other diseases.

For purposes of the proposed packaging rule, ASH strongly urges CMS to reconsider the classification of I131-Tositumomab as a diagnostic radiopharmaceutical and to treat all doses of I131 Tositumomab as therapeutic. With respect to the level of payment, ASH is not presenting specific recommendations as to how CMS can best fix this problem. The Society understands that this issue was presented at the meeting of the APC Advisory Committee on September 6, 2007 and that several options were proposed. This included paying for the agent as a drug and not as a radiopharmaceutical so that it would be paid at the rate of 106 percent of average sales price (ASP). ASH further understands that the manufacturer has indicated a willingness to submit quarterly ASP prices. Also, the APC Advisory Committee and the manufacturer urged CMS to consider establishing a "composite" APC reflecting the full costs for the entire course of therapy including all the procedural services, radiopharmaceuticals, drugs and supplies. All of these methods would seem promising. However, what is critical is that CMS find ways to substantially improve the payment so that patients are not deprived access to this valuable cancer treatment.

Thank you again for the opportunity to offer these comments. If ASH can provide any further assistance including furnishing the actual survey instrument and survey data, please contact Carol Schwartz, ASH Senior Manager of Policy and Practice, at 202-292-0258 or at *cschwartz@hematology.org*.

Sincerely,

Andrew Schafer

Andrew I. Schafer
President

MGI
PHARMA

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MGI PHARMA
5775 West Old Shakopee Road
Suite 100
Bloomington, Minnesota 55437-3174

(Telephone) 952-346-4700
(Facsimile) 952-346-4800
www.mgipharma.com

September 13, 2007

Mr. Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates (CMS-1392-P)

Dear Mr. Weems:

MGI PHARMA, Inc. ("MGI") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Service ("CMS") proposed rule to revise payment policies under the Hospital Outpatient Prospective Payment System ("OPPS") for 2008 (the "Proposed Rule").[1] MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi® (palonosetron hydrochloride) injection and Dacogen™ (decitabine for injection) are two of MGI's products that are made available in the hospital outpatient setting.

MGI PHARMA seeks to ensure that Medicare reimbursement for oncology drugs and other innovative pharmaceutical products are adequate to support Medicare beneficiary access to these therapies in the hospital outpatient setting. Our comments therefore focus on the Proposed Rule's provisions addressing reimbursement for drugs and biologicals. In particular, MGI recommends that CMS:

- Clarify its proposal to bundle payments for items and services "integral" to a procedure;
- Maintain reimbursement for non-pass-through drug payments at average sales price ("ASP") plus 6 percent; and
- Not increase the packaging threshold.

Our detailed comments include:

I. CMS Should Clarify its Proposal to Bundle Payments for Items and Services "Integral" to a Procedure [HOPPS: Packaged Services]

CMS proposes packaging the payment for certain "dependent" items and services that are integral to other independent services in the following seven categories: guidance services; image processing services; intraoperative services; imaging supervision and interpretation services; diagnostic radiopharmaceuticals; contrast media; and observation services. In other

[1] 72 Fed. Reg. 42,627 (Aug. 2, 2007).

words, separate payment would no longer be available for these "dependent" items and services.

We believe that CMS should clarify its standards for determining which items and services are "integral to" other procedures, since the preamble to the Proposed Rule offers only vague description of the standards. For instance, with regard to dependent guidance procedures, CMS states only that the codes selected "support the performance of an independent procedure and they are generally provided in the same operative session as the independent procedure." Use of such broad, undefined standards could result in the inappropriate inclusion of items and services in the packaging policy.

We recommend that CMS ensure that this provision is applied on as limited a basis as possible to prevent the packaging policy from adversely impacting the ability of hospitals to furnish necessary medical services. Moreover, CMS should ensure that payment for the "independent" procedure fully captures the cost of the packaged "dependent" item or service. Finally, we request that CMS address the impact, if any, of this policy on procedures and items that currently are treated together, such as sedation and anesthesia services and the primary procedure.

II. CMS Should Not Reduce Medicare Payment for Non-Pass-Through Drugs and Biologicals [OPPS: Specified Covered Outpatient Drugs]

CMS is proposing to reduce Medicare payments for non-pass-through drugs in the hospital setting from ASP plus six percent to ASP plus five percent. CMS intends for this reduced amount to continue to cover both the drug/biological acquisition costs and pharmacy overhead. CMS proposes to instruct hospitals to begin reporting pharmacy overhead charge on an uncoded revenue code line on the claim beginning in CY 2008, and eventually CMS intends to package pharmacy overhead costs for drugs and biologicals into the payment for the associated procedure.

We are concerned that CMS's proposed reduction in reimbursement will not adequately compensate hospitals for their drug acquisition and pharmacy handling costs. This could jeopardize hospitals' ability to provide Medicare patients with access to needed oncology treatments in the outpatient setting.

Moreover, we believe it is inappropriate to reimburse hospitals at a lower rate than physicians' offices for the same drug products. CMS has expressed concerns in the past regarding site-of-service payment differentials. Adopting the proposed reduction in reimbursement for drugs and biologicals in the OPPS setting could result in Medicare payment policy influencing treatment determinations.

We therefore urge CMS to reimburse non-pass-through drugs at least at ASP plus six percent, consistent with the recommendations of the Advisory Panel on APC Groups at its March 2007 meeting. Likewise, CMS should not consider future reductions in payments for non-pass-through drugs and biologicals until the agency has adopted reforms that adequately compensate hospitals for pharmacy overhead costs outside of the drug payment rate.

III. CMS Should Not Increase the Packaging Threshold [OPPS: Packaging Drugs and Biologicals]

In the Proposed Rule, CMS proposes to increase the current threshold required for separate payment of outpatient drugs, biologicals, and radiopharmaceuticals under the HOPPS. Specifically, CMS would adjust the current $55 packaging threshold by the Producer Price Index ("PPI") for prescription drugs, rounded to the nearest $5 increment. CMS estimates that using this methodology, the threshold for 2008 would be $60.

We believe that the threshold should be maintained at $55 to preserve separate payment for relatively expensive drugs and biologicals. CMS already increased the threshold by $5 for 2007; an additional $5 increase for 2008 would represent a 20 percent increase in the threshold in just two years. CMS is not required to impose an annual adjustment to the threshold amount, and escalating the amount every year makes it harder for hospitals to afford to provide important medical therapies. Instead, continuing the current threshold amount would better compensate hospitals for furnishing drugs and biologicals, preserve stability in payment policy, and safeguard Medicare beneficiary access to medically-necessary drugs and biologicals.

We also note that the Advisory Panel on APC Groups has recommended that CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes, and to instead reimburse these products separately. We believe this proposal has merit, and we recommend that CMS consider the Advisory Panel's proposal as an alternative to annual updates to the threshold amount.

We appreciate your consideration of our comments and would be pleased to answer any questions you may have.

Sincerely,

Dave Melin, Vice President
Corporate & Government Affairs
MGI PHARMA, Inc.

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

September 12, 2007

RE: CMS-1392-P

On behalf of the 200 hospitals in Illinois, the Illinois Hospital Association (IHA) thanks you for the opportunity to provide comment on the Outpatient Prospective Payment System (OPPS). In particular, this set of comments will be directed to the proposed performance measurement system starting January 1, 2008.

The Illinois hospitals are deeply committed to assessing and reporting performance as a critical means to improving the quality of care for all patients. IHA and its members have supported the efforts of the Centers for Medicare and Medicaid Services (CMS) in its efforts to collect Hospital Quality Alliance process and outcome measurements and HCAHPS. Throughout the years, there has always been a discussion on a challenging but somehow manageable approach to reporting of this information.

With the proposed rules to outpatient, it appears that many of the lessons learned have not been applied to the outpatient performance measurements. The performance measurements have not been tested nor have CMS data management and collection systems been tested to determine ability to receive and properly edit and report out information.

Given the significance of the issues raised below, we request that CMS phase in the reporting of outpatient performance measurements for OPPS during calendar year 2008:

Measurement Issues

1. *Measurements have not been approved by National Quality Forum*, therefore the validity, reliability, accuracy, appropriateness have not been assessed.

2. *DRAFT measurement specifications were only released for these measurements on September 5th* and are just being vetted for public comment.

3. While the *DRAFT specifications focus on emergency care patients, there is no mention of observation care patients* which is problematic given the criteria CMS has established for observation care services versus inpatient admissions.

Headquarters
1151 East Warrenville Road
P.O. Box 3015
Naperville, Illinois 60566
630.276.5400

Springfield Office
700 South Second Street
Springfield, Illinois 62704
217.541.1150

www.ihatoday.org

4. While some of the measurements mirror some of the services assessed on inpatient side, the *outpatient information reporting systems are quite different.*
5. Most hospitals do not have the same information reporting systems for emergency and observation care as they do for inpatient care. Since hospitals are not using standard performance measurements or collection systems on the emergency and outpatient setting, *it will take time to have the health information technology vendors that service the outpatient care settings of hospitals to incorporate the variables, values, and intervention processes for reporting out.*

6. *Most vendors are unaware of the draft specifications recent release and given the controversy and measurement methodology issues, vendors will not begin programming until final specifications are issued.*

7. *Hospitals cannot afford to perform retrospective reporting of data in the emergency or observation setting as the volume of patients is significant.* Furthermore, while it may appear to be less challenging to some to collect similar types of data in the inpatient and outpatient settings, there are differences in reimbursement and therefore, higher per case costs in collecting outpatient data.

8. *The volume of patients in the Ed and Observation care settings are significant – yet, the volume of data and number of data elements required to generate one process measurement remains constant between inpatient and outpatient settings.*

System Performance Issues
Given the experience with the CMS warehouse processing and the continuing inpatient data processing errors and problems, hospitals are extremely concerned about the volume of data errors and amount of time to be expended by providers on an untested system. Hospitals have spent countless hours identifying problems, waiting for corrections, and in some instances having to appeal validation results as a result of warehouse processing problems.

For CMS to move ahead with an untested system would be a huge financial burden for providers to bear as we are confident there will be problems in the warehouse and providers will bear the cost of re-work and hospital staff hours spent on identifying and verifying issues.

Validation
The validation process on the inpatient side is fraught with CDAC errors and with little room for hospitals to effect change on CDAC errors. Hospitals are very concerned that CDAC staff have not been trained, and given history with ongoing CDAC errors, it is most likely significant issues with validation will only increase. As hospitals cannot appeal scores 80% or greater, even knowing there are obvious CDAC errors, this will again be another source of wasted hospital resources and frustration.

No Statutory Requirement for Start Up on January 1 2008

While CMS must begin OPPS payment based upon OPPS performance data starting October 1, 2008, there is nothing in statute that states hospitals or CMS must begin collecting data starting January 1, 2008 and therefore we urge CMS to delay implementation.

Closing Remarks

IHA and its member hospitals remain totally committed to performance reporting and public accountability. It is important that the information provided to consumers is accurate, complete, timely, valid, reliable, and reflective of the hospital services.

Given all of the issues raised, we request that CMS proceed with its measurement validity, reliability, and accuracy review by the National Quality Forum and the public vetting process. We also ask that CMS review the issues raised in this communication and address the concerns expressed by IHA and its 200 member hospitals.

If you need clarification on any of the issues raised, please contact me by e-mail at pmerryweather@ihastaff.org or by telephone at 630-276-5590.

Thank you --- we look forward to working together to advance the understanding of health care services to all of our communities.

Sincerely,

Patricia Merryweather
Senior Vice President
Illinois Hospital Association
1151 E. Warrenville Road
Naperville, Illinois 60566
Pmerryweather@ihastaff.org
630-276-5590

AfPA

THE ALLIANCE FOR PATIENT ACCESS

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September 12, 2007

Kerry Weems
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; CMS-1392-P.

Dear Mr. Weems:

As chairman of the Alliance for Patient Access (AfPA), a national network of physicians whose mission is to ensure and protect patient access to approved medical treatments in the U.S., and as a neurologist who has been practicing in an academic setting for 13 years, I am pleased to submit comments on the proposed Hospital Outpatient Prospective Payment System update for 2008, particularly on the agency's proposals concerning **Packaged Services**, **Specified Covered Outpatient Drugs**, and **Implantation of Spinal Neurostimulators**.

OPPS: Packaged Services

Generally, AfPA concurs that increased packaging of services encourages hospitals to use items and services more judiciously, and that CMS should seek to package payment wherever appropriate. However, sweeping attempts to package payment for broad categories of services, as CMS is now proposing to do, is likely to create more problems than would be solved. CMS should continue to evaluate packaging determinations on a procedure-specific, case-by-case basis to ensure that packaging is medically and economically justified and does not create inappropriate and problematic financial incentives.

We are especially concerned about CMS's proposal to package payment for electrodiagnostic guidance (codes 95873 and 95874) for chemodenervation procedures (codes 64612-64614). Our physician members frequently use real-time electrodiagnostic procedures—electromyography or electrical stimulation to guide needle placement when performing chemodenervation procedures. In these procedures, the location of the injection is critical to success of the procedure, and the physician must ensure that the chemodenervation agent is delivered to the precise location in need of treatment. Chemodenervation involves injection of chemodenervation agents, such as botulinum toxin type A, to control the symptoms associated with dystonia. Dystonia is a

movement disorder that causes muscles to contract and spasm involuntarily. By injecting chemodenervation agents directly into the muscle tissue, the physician can block the nerve impulses that trigger muscle hyperactivity. However, for the treatment to be effective, the chemodenervation agent must be delivered to a precise location. As such, physicians often use electromyography or electrical stimulation guidance to guide the needle and ensure that the chemodenervation agent is injected in the most appropriate location to achieve the desired outcome. However, electrodiagnostic guidance procedures are not always required. Whether these procedures are medically necessary depends upon a number of factors, including the indication for chemodenervation, the specific muscles to be injected, and the cognitive ability of the patient.

We are concerned that CMS's proposal to package payment for the electromyography or electrical stimulation guidance may lead hospitals to discourage utilization of guidance equipment, even where medically indicated. Hospitals that do not use guidance services or that severely limit the utilization of these guidance services will reap a financial windfall for their decision.

We are also concerned that patient-centered hospitals that do not allow financial considerations to cloud medical decisionmaking would be penalized for their policy. Under CMS's proposal, the combined payment amount for the injection and guidance would be less than the total amount presently available when these services are paid separately. In fact, the combined payment amount for the injection and guidance would be approximately 15 percent less than the total amount presently available when these services are paid separately. As such, the hospital that incurs the cost of the guidance procedure will not be adequately reimbursed for the service furnished.

For the foregoing reasons, AfPA encourages CMS to reconsider its proposal to package electromyography and electrical stimulation guidance procedures (codes 95873 and 95874) because these guidance procedures do not accompany the base injection procedure in every instance and are furnished only when medically necessary.

OPPS: Specified Covered Outpatient Drugs

AfPA is also troubled by CMS's proposal to reduce payment for injectable drugs furnished in the hospital setting to 105 percent of average sales price. We are primarily concerned that reducing payment in this manner could under-reimburse many hospitals for their drug-related costs. While ASP may theoretically reflect the average price hospitals pay for drugs, and adequately compensate many hospitals for their purchasing-related costs, not all hospitals can acquire drugs and biologicals at the average sales price. In addition, a hospital's acquisition costs go beyond the simple purchase price for the drug or biological. Hospitals also incur overhead costs associated with storing and furnishing drugs and biologicals. These costs may be substantial for complex biologicals that require special handling. By reducing the supplemental payment above ASP from 6 percent to 5 percent, CMS is potentially under-reimbursing hospitals for these overhead and handling costs related to acquisition of drugs and biologicals. To the extent hospitals are unable to recoup the cost of purchasing, storing and furnishing pharmaceuticals, they may be forced to make hard decisions about which drugs they are capable of storing. We

oppose any proposal that could limit a vital access point for patients who depend on these therapies.

Perhaps most troubling is that CMS is proposing to make this change without clearly setting out any underlying data to support it. CMS does not provide adequate justification for this reduction other than to state that this payment amount is consistent with CMS's estimate of hospital acquisition costs. If CMS believes that hospital costs (total costs including overhead and handling) are lower in the hospital setting than in the physician's office, CMS should collect this data, present it to the public for comment and also consider the potential impact of different payment formulae on patient access before adopting any change in the payment formula.

Moreover, we are concerned about the payment disparity between hospital and physician office settings that would result from this change. In recent years, payments for physician-injected drugs have been the same across the two settings, *i.e.,* 106 percent of ASP. This has avoided the experiences of a few years back where some patients were being shifted between hospital outpatient and physician office settings depending upon which setting provided payment that more adequately covered provider acquisition costs. Payment parity should be maintained to ensure adequate access to therapies in both settings.

We request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain payment at 106 percent of ASP.

OPPS: Implantation of Spinal Neurostimulators

In the 2008 CMS Proposed Hospital Outpatient Payment System rule, CMS proposes to pay hospitals the same rate for rechargeable and non-rechargeable neurostimulators when implanted in hospital outpatient departments. The cost differential (according to CMS's claims data) between the two technologies is approximately $6,500. This is a meaningful difference that warrants separate reimbursement. We are concerned that this proposal, if implemented, will cause hospitals to make treatment decisions based on economics rather than the best course of care for patients who suffer from chronic, intractable pain.

Rechargeable neurostimulators offer a breakthrough in treatment for patients with complex pain over multiple areas. The enhanced capabilities of rechargeable technology allow physicians to manage patients' pain patterns instead of worrying about depleting the battery of conventional, non-rechargeable devices. Rechargeable devices eliminate the need for battery replacement surgeries associated with non-rechargeable devices, sparing patients the risk and inconvenience associated with multiple surgical procedures and increasing long-term efficiency for the Medicare program.

The importance of rechargeable neurostimulation technology was previously acknowledged by CMS when it granted the device new-tech add-on payment status in the hospital inpatient setting and pass-through status in the hospital outpatient setting. These additional payments to hospitals made it possible for patients with chronic pain to benefit from rechargeable pain-relief technology. With the conclusion of outpatient pass-through status, however, CMS is now proposing to pay the same amount for rechargeable neurostimulators as it does for all other non-

rechargeable devices. We are concerned that the proposed payment policy is insufficient and may jeopardize patient access to this important therapy.

We urge CMS to create a new APC to provide adequate payment for rechargeable technologies to ensure appropriate access to rechargeable neurostimulators.

* * * * *

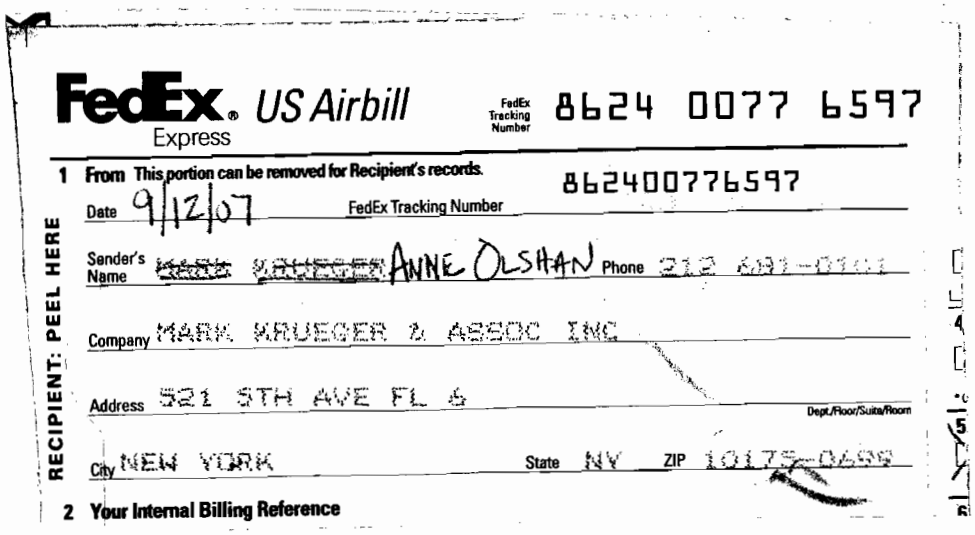
In summary, AfPA encourages CMS to

- Maintain separate payment for electromyography and electrical stimulation guidance procedures (codes 95873 and 95874);
- Maintain the current payment formula for physician-injectable drugs for 2008 at 106 percent of ASP.
- Create a new APC to provide adequate payment for rechargeable technologies

Thank you for your consideration of our comments.

Sincerely yours,

David Charles, MD
Chairman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ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

September 14, 2007

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

RE: File code **CMS-1392-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates**

Dear Acting Administrator Weems:

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to submit these comments on the proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) for calendar year (CY) 2008 as published in the Federal Register (FR) on August 2, 2007 ("the proposed rule"). ASCO is the national organization representing physicians who specialize in the treatment of cancer. ASCO is committed to advancing policies that provide access to high-quality cancer care and accordingly offers comments on the OPPS proposed rule.

ASCO's primary recommendations center on incorporating additional codes into the bypass list. If these recommendations are implemented in 2008, a greater number of claims would be available to calculate APC weights which would result in more accurate payments. ASCO also offers comment on CMS's plans to increase packaging in the future, as well as the proposal to pay for drugs and pharmacy overhead costs in the hospital outpatient setting at Average Sales Price (ASP) +5%.

Specific detail and discussion on each of these comments, and other items of interest, are outlined below.

OPPS: Drug Administration

Bypass Codes: Second or Subsequent Drug Codes

ASCO recommends that codes 90767, 90768, 90775, 96411 and 96417, as shown in the table below, be included in the Bypass Code list for 2008 as chemotherapy and supportive care regimens increasingly entail administration of multiple drugs in the same treatment sessions and claims for these procedures should be used in rate setting.

90767	Tx/proph/dg addl seq iv inf
90768	Ther/diag concurrent inf
90775	Ther/proph/diag inj add-on
96411	"Chemo, iv push, addl drug"
96417	Chemo iv infs each addl seq

Under current policy, if correct coding guidelines are followed and these "additional drug" codes are reported to reflect administration of multiple drugs in the same treatment session, multiple procedures would be reported on the vast majority of claims and therefore discarded for rate setting purposes. Amending the Bypass Code list to include these procedures will treat these codes as single claims and increase the amount of claims data used in rate setting in 2008. Packaged items appearing with drug administration services would then, in theory, be packaged into the first drug administration code billed and the second drug administration would cover the costs of that service alone.

CMS currently includes drug administration codes for "each additional hour" of infusions on the Bypass Code list with the rationale that these codes are associated with the corresponding drug administration code for the first hour of an infusion and include little, if any, packaging of their own. Similar to the "each additional hour" concept, when the new CPT® codes for drug administration were implemented in 2006, these codes were added to the OPPS system for drug administration procedures. These codes reflect a second, subsequent, or concurrent drug added to the episode of care. According to 2006 claims data, these new codes were used with low frequencies and, therefore, did not meet the criteria for inclusion on the Bypass Code list.

With respect to code 90768, the APC panel recommended that CMS pay separately for this code; however, CMS is not accepting the recommendation to establish a separate APC payment for this service and instead proposes to continue packaging this code in 2008. ASCO believes that including this code on the bypass list, rather than packaging it, would be a more appropriate option and consistent with treatment of other add-on and additional hour codes that are already bypassed and thus treated as single claims.

ASCO recommends that codes 90767, 90768, 90775, 96411 and 96417 be included in the Bypass Code list for 2008. We believe that use of these codes will increase in 2007 and 2008 as hospitals transition away from C codes and fully implement the CPT drug administration codes. It should be possible to set a rate for these codes based on the median cost associated with the procedure in the limited number of claims for 2006. The median can be updated in the future as more claims data accumulate.

OPPS: Packaging Drugs and Biologics

Anti-Emetic Products
ASCO supports CMS's proposal to continue exempting the oral and injectable forms of 5HT3 anti-emetic products from packaging, thereby making separate payment for all of the 5HT3 anti-emetic products (*i.e.,* J1260, J1626, J2405, J2469, Q0166, Q0179, Q0180) regardless of the proposed CY 2008 $60 packaging threshold. As CMS states, "chemotherapy is very difficult for many patients to tolerate, as the side effects are often debilitating" and "in order for Medicare beneficiaries to achieve the maximum therapeutic benefit from chemotherapy and other therapies with side effects of nausea and vomiting, anti-emetic use is often an integral part of the treatment regimen."[1] ASCO applauds CMS's recognition that Medicare payment rules should not "impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."

Anti-Cancer Chemotherapy Drugs
Similar to CMS's position on anti-emetic products, the therapeutic effectiveness of anti-neoplastic drugs, and the extent to which they cause debilitating side effects and/or potential interactions, is patient specific and dependent upon the type, dose and schedule of the cancer chemotherapy regimen undertaken. A

[1] 42 CFR Parts 410, 411, 414 et al. page 42733.

patient's course of cytotoxic therapy (either as monotherapy or as a combination of drugs) is based on the medical decision-making of the physician(s) involved, the type and stage of the cancer in question, patient characteristics/preferences, and scientific evidence in the medical journals. Given the array of clinical and patient specific parameters involved in treating cancer patients, these drugs would not serve as an appropriate class of products to package under Medicare payment rules. While ASCO recognizes that there currently are instances where certain anti-neoplastic agents would fall under the CY 2008 $60 threshold and thus be packaged, we do not support application of this concept to anti-cancer chemotherapy drugs, particularly if expanded on a wider scale.

CMS has proposed to package certain diagnostic radiopharmaceuticals and contrast agents, based partially on the justification that these products are more ancillary and supportive in nature. Opposite from this, the primary purpose of providing cancer chemotherapy agents is the anti-neoplastic treatment derived from the drug itself. Cancer chemotherapy treatment is neither ancillary nor supportive, and accordingly the packaging concept should not apply to this class of drugs. Packaging cancer chemotherapy drugs would "impede a beneficiary's access to the particular..." anti-neoplastic "that is most effective for him or her as determined by the beneficiary and his or her physician."

Since the agency seeks comment on how to increase packaging of payment for drugs, biologics and radiopharmaceuticals, ASCO finds it is important to emphasize our belief that the agency should consider treating chemotherapy drugs in much the same way that it treats anti-emetics. We believe that packaging is generally inappropriate for chemotherapy products and that any efforts to expand the packaging of drugs and biologicals should exclude chemotherapy agents and other medicines that are often used by oncologists. Further bundling of drugs and biologicals used to treat cancer patients would be inappropriate and would negatively impact beneficiaries' access and care. Furthermore, significant public and private resources are annually devoted to cancer care research, resulting in part, in a number of new anti-neoplastic agents available to patients and their physicians on a regular basis. The CMS payment methodology for reimbursement of packaged drugs and biologicals relies on data that can be two years old or more, making this methodology ill-designed for the rapidly changing landscape of oncology.

In addition, the same reasons described under the proposal to include additional procedures to the bypass list also support the separate reimbursement for anti-neoplastic agents. By definition, chemotherapy regimens of one or more drugs will have more than one major procedure (under the current proposed rule) and likely more than one drug that may or may not be packaged. To increase the ability to create single claims from this special clinical circumstance, ensuring that drugs are separately paid will eliminate them as a cause of a claim being classified as a multiple bill and therefore not used for rate setting. Moreover, if this policy is combined with the bypass policies proposed in the previous section, many more claims will be able to be used to set the rates for chemotherapy administration services, and the accuracy of payment associated with these services will increase.

ASCO will continue to monitor CMS's packaging rules, and we are available to work with CMS as the agency considers how to increase packaging in the future. As the agency notes, CMS is not "required to treat all classes of drugs in the same manner with regard to whether they are packaged or separately paid."[2] Similar to its policy on anti-emetics, ASCO strongly encourages CMS to use its discretion and refrain from further packaging any anti-neoplastic drugs in future rule makings to protect beneficiary access to high quality care and advances in cancer treatment. We further believe that this policy should extend to those products typically used in chemotherapy supportive care regimens. At a minimum, CMS

[2] 42 CFR Parts 410, 411, 414 et al. page 42737.

should not attempt to package supportive care products with per day costs in excess of the OPPS drug packaging threshold.

OPPS: Payment for Diagnostic Radiopharmaceuticals

With regard to the CMS proposal to package all diagnostic radiopharmaceuticals, ASCO believes that because of the large variation in underlying costs for these products packaging is not appropriate. Separate payment should be made according to the general packaging policy for drugs and biologicals.

OPPS: Specified Covered Outpatient Drugs

Proposed Payment Policy: Pharmacy Overhead and ASP +5%

For CY 2008, CMS proposes to require hospitals to remove pharmacy overhead charges from the charge for drugs or biologicals and separately report the pharmacy overhead charges on an un-coded revenue code line on the claim. Under this proposal, hospitals would report a charge for the drug and a separate charge for the pharmacy overhead associated with that drug beginning in 2008. According to CMS, this proposal could, for example, allow CMS to package pharmacy overhead costs into payment for drug administration rather than packaging pharmacy overhead costs into payment for the drug itself starting in 2010. In the interim, CMS proposes to continue to provide a bundled payment for drugs and pharmacy overhead costs at ASP +5 percent, while still requiring hospitals to separately report the drug and pharmacy overhead charge.

ASCO is extremely concerned by the proposal to pay for drugs and pharmacy overhead costs in the hospital outpatient setting at ASP +5%. Providing a packaged payment for drugs and pharmacy overhead costs at this reduced rate does not adequately cover the costs incurred by hospitals to acquire and handle drugs.

ASCO supports efforts to gather more information about pharmacy overhead costs in the outpatient hospital setting. However, we are concerned that efforts to gather this information may be hampered by confusion and administrative burdens at the hospital level. While the proposal to separately report the pharmacy overhead charge on an un-coded revenue code line on the claim may appear conceptually feasible it could be practically very difficult for hospitals to achieve. We are concerned that hospital compliance with the new requirement will be far from universal and that the overhead data gathered from the proposed requirement may not accurately represent pharmacy department costs.

ASCO believes that reimbursement for drug acquisition cost in the hospital setting should remain at ASP + 6%. We believe that equilibrating payments for product costs will provide a neutral set of reimbursement incentives that will minimize potential distortions based on payment differentials across sites of service.

IVIG Pre administration-Related Services

In 2006 and 2007 CMS reimbursed hospitals for IVIG pre administration costs through G0332 (services for intravenous infusion of immunoglobulin prior to administration of immunoglobulin). This additional payment helps to mitigate the adverse financial impact that many providers experience in obtaining IVIG for their patients. ASCO appreciates that CMS will continue to provide separate payment for IVIG pre administration related services in 2008, however is concerned that the reimbursement rate will be cut substantially. There continue to be significant problems in obtaining IVIG for less than the Medicare

payment amount. In an effort to help mitigate these problems, we encourage CMS to maintain reimbursement for G0332 at existing 2007 levels.

OPPS: Payment for Therapeutic Radiopharmaceuticals

ASCO agrees that CMS should continue to make separate payment for therapeutic radiopharmaceuticals and that these items, which are used for treatment, should not be packaged.

However, we are concerned that CMS' proposal to base payments for these products on mean cost findings will result in reduced hospital reimbursement and potentially reduced patient access to radiopharmaceutical therapies. ASCO believes that therapeutic radiopharmaceuticals should continue to be paid on a reasonable cost basis. As proposed, the rates for therapeutic radiopharmaceuticals will be significantly lower than 2007, and for some hospitals are likely to be lower than their acquisition costs. We are particularly concerned that availability of tositumomab (Bexxar) and ibritumomab tiuxetan (Zevalin) not be adversely affected by this proposal.

Reporting of Quality Measures

For 2009, CMS is proposing ten quality measures to be reported under the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) and is considering other measures that it might adopt for 2010 and later years. ASCO supports the adoption of quality measures related to cancer care that are reviewed and endorsed by the National Quality Forum, as part of the HOP QDRP.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Joseph S. Bailes

Joseph S. Bailes, MD
Chair, Government Relations Council

Heart Rhythm Society[SM]

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VIA ELECTRONIC MAIL

September 14, 2007

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: [CMS-1392-P]

Dear Administrator Weems:

The Heart Rhythm Society welcomes the opportunity to provide written comments on the notice of proposed rulemaking CMS-1392-P entitled "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," published in the *Federal Register* on August 2, 2007. Our comments focus on the proposal to implement a composite APC for evaluation and ablation procedures, and to package certain intra-operative codes for payment in calendar year (CY) 2008.

HRS is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Founded in 1979, HRS is the preeminent professional group representing more than 4,500 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and their support personnel. HRS' members perform electrophysiology studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers and cardioverter defibrillators (ICDs) in patients who have indications for these life-saving devices. After device implantation, heart rhythm specialists then monitor these patients and their implanted devices.

It is our interpretation, that the proposed encounter-based composite APC is appropriate, as it will provide a single payment for certain common combinations of component cardiac electrophysiologic services performed on the same date of service, and enables CMS to use more valid and complete claims data to establish payment rates that will better capture the costs of these combination services.

1400 K Street NW, Suite 500 | Washington, DC 20005 | USA | Phone: 202-464-3400 | Fax: 202-464-3401 | info@HRSonline.org | www.HRSonline.org

CMS is also proposing to unconditionally package other CPT codes under the grouping of intra-operative services for the CY 2008 OPPS. These codes (93609, 93613, 93621, 93622, 93623 and 93662) are all CPT add-on codes that are often reported with cardiac electrophysiologic evaluation and ablation services. We are concerned, however, with the packaging of intracardiac echocardiography (ICE) (CPT 93662) which is reported as an add-on code for cardiac electrophysiology and interventional cardiology procedures that require a transseptal approach. For CPT 93621, 93622, 93651 or 93652, ICE is used to identify the area of the atrial septum where needle puncture can be safely performed and thus significantly reduce the risk and complications from the procedure. ICE is also a valuable tool in guiding the safe delivery of ablation lesions, and for monitoring of possible pericardial effusion. ICE is currently paid separately under APC 0670 with a payment rate of $1984.52. This is a low volume procedure offered only in a limited number of hospitals which provide the most state-of-the art care to the most complex patients; therefore, we believe that packaging this low-volume procedure will contribute inadequately to the medians of the composite APC or to the individual APC medians. Furthermore, the impact of the packaged payment for this supportive procedure will be concentrated in the small subset of hospitals that have invested in this expensive technology. We recommend that this procedure continue to be paid separately under the OPPS for CY 2008.

In the proposed rule, CMS indicates that the proposed composite APCs may serve as a prototype for future creation of more composite APCs, through which OPPS payment could be provided for other types of services in the future. While we believe that this approach may be appropriate where the claims data show that combinations of services are commonly furnished together, we recommend that CMS proceed with caution regarding broad application of this methodology. Any further development of composite APCs should be accompanied by a clear, transparent process and data for identifying and calculating future composite APCs should be included with documented justifications. Additionally, it is important that composite APCs are designed in a manner that sufficiently accounts for the resources associated with performing the common combinations of services.

HRS appreciates this opportunity to offer our comments. If you have any specific questions regarding our recommendations, please contact Lisa Miller-Jones, Director of Reimbursement and Regulatory Affairs at (202) 464-3433 or at lmiller-jones@HRSonline.org.

Sincerely,

Bruce D. Lindsay, MD, FHRS
President, Heart Rhythm Society

Government Affairs Division

Baxter Healthcare Corporation
1501 K Street, N.W.
Suite 375
Washington, D.C. 20005
202.508.8200
Fax: 202.508.8201

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Baxter

September 10, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Department of Health and Human Services
Washington, D.C. 20201

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

2007 SEP 12 PM 2:23

1. BONE MARROW AND STEM CELL PROCESSING SERVICES
2. OPPS PACKAGING DRUGS AND PHARMACEUTICALS
3. OPPS SPECIFIED COVERED OUTPATIENT DRUGS
4. SERVICE SPECIFIC PACKAGING ISSUES

Dear Kerry Weems:

Baxter Healthcare Corporation (Baxter) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed regulation, entitled "Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment,"[1] ("Proposed Rule") released July 12, 2007. Baxter is a global diversified healthcare company that develops products and therapies to make a meaningful difference in the lives of people with hemophilia, kidney disease, immune disorders and other chronic and acute conditions. The company operates in three segments: Bioscience, Medication Delivery and Renal. *BioScience* develops biopharmaceuticals, biosurgery products, vaccines and blood collection products and technologies. *Medication Delivery* provides intravenous solutions and specialty products used for fluid replenishment, anesthesia, nutrition, pain management, antibiotic therapy and chemotherapy. *Renal* develops products and services to treat end-stage kidney disease.

1. Bone Marrow and Stem Cell Processing Services

Background--Autologous adult stem cell selection therapy is currently used for oncology treatment following chemotherapy for various forms of cancer (e.g.,

[1] 72 Fed. Reg. No. 148 (August 2, 2007).

non-Hodgkin's lymphoma, breast cancer) and other treatments.[2] For oncology, it enables re-establishment of bone marrow function and blood cell production for cancer indications after high dose chemotherapy. Historically, CMS has recognized Healthcare Common Procedure Code System (HCPCS) code G0267 (*Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s)*) to report the depletion of hematopoietic progenitor cells.[3] CMS has instructed hospitals to bill for these services using the HCPCS code rather than the six more specific Current Procedure Terminology (CPT) codes that describe such services. CMS currently assigns HCPCS G0267 to Ambulatory Payment Classification (APC) 110 (Transfusion), with a payment rate of $212.58.

Proposed--For CY 2008, CMS proposes to recognize the six specific CPT codes (CPT 38210-38215) for bone marrow and stem cell processing services in the hospital outpatient prospective payment system (HOPPS). The agency notes that current hospital resources associated with these procedures may vary widely and that the total volume of these procedures, while still relatively small, has been increasing over the past several years. CMS believes that, by recognizing the six CPT codes, it will be able to pay more appropriately for these services in the future. For CY 2008, CMS proposes to assign the newly recognized CPT codes to APC 110, with a proposed payment rate of $222.44, until such time as it has more specific hospital resource data to assess possible reassignment.

Response--Baxter supports CMS's proposal to recognize more specific coding for bone marrow and stem cell processing services under HOPPS, rather than the single HCPCS code (G0267). The granularity in coding represented by CPT codes 38210-38215 cannot be adequately reflected through the use of a single HCPCS code. Each of the CPT codes represents a unique processing service with widely varying resource requirements. In fact, additional CPT codes may be required in the future to represent the range of procedures.

However, we have significant concerns about the proposed assignment of these codes to APC 110. Not only do these CPT codes, currently described by HCPCS G0267, represent a range of procedures with widely disparate costs, these codes have modest volume compared with other procedures assigned to APC 110. According to the CMS HOPPS median cost file, claims for G0267 represent less

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[2] Prentice, D. "Adult Stem Cells" Appendix K in *Monitoring Stem Cell Research: A Report of the President's Council on Bioethics* (Washington, DC: Government Printing Office, 2004), 309-346.

[3] In adult organisms, the stem cells and the progenitor cells act as a repair system for the body. The term progenitor cell refers to immature or undifferentiated cells. While progenitor cells share many common features with stem cells, the term is far less restrictive. Hematopoietic stem cells are found in the bone marrow of adults. Cells can be obtained directly by removal from the hip using a needle and syringe, or from the blood following pre-treatment with cytokines, such as granulocyte colony stimulating factors, that induce cells to be released from the bone marrow compartment. In recent years, the development of media used to expand and mature adult stem cells has greatly increased the number of candidates eligible as well as the success rate of adult stem cell therapy.

than one percent of the single frequency claims included in the calculation of payment for APC 110. Instead, APC 110 is dominated by transfusion procedures (CPT 36430), with mean cost that are less than one-tenth the cost of reagents alone for the higher cost T-cell and tumor cell depletion procedures. The continued inclusion of stem cell processing services in the Transfusion APC 110 perpetuates a strong financial disincentive for hospital adoption of these services. For example, the costs of procedures for removing T-cells or tumor cells (CPT codes 38210 and 38211, respectively) are significantly higher than the costs of removing red blood cells or platelet depletion. For these two codes, CPT 38210 and 38211, placement in APC 110 would clearly violate the 2 times rule. The median costs of these two procedures will much higher than twice the lowest median cost for an item or service in APC 110 ($119.33).

Specifically, 38210 (T-cell depletion) and 38211 (tumor cell depletion) are high cost services, which are performed by only a limited number of facilities at the current time. Data collected by the American Society of Hematology (ASH) suggests that the reagent kits alone for Codes 38210 and 38211 used for these services cost from $7,000 to $7,900 per patient with clinical staff costs from $270 to $1,400. Baxter urges CMS to rely on alternative methods for determining HOPPS payment amounts for these services. Specifically, we request that CMS consider one of two options for adult stem cells: the first, cost-based payment methodology to establish appropriate payment level(s) for these two CPT codes for bone marrow and stem cell processing services; the second, reassignment to another APC, rather than continued assignment of these procedures to APC 110 in CY 2008.

- **OPTION 1:** Reimburse CPT codes 38210-38211 using a cost-based payment methodology based on a hospital's charges reduced to cost using CCR methodologies for blood products. This will allow time for hospitals to adapt to these coding changes, for CMS to collect improved claims data for stem cell processing services, and to more fully analyze charge compression issues unique to stem cell processing services.

- **OPTION 2:** Given the proposed $222 payment rate would cover only a small portion of the costs, another option would be to place these two codes into a higher paying APC and Baxter would suggest, APC 0112, Apheresis and Stem Cell Procedures, with a payment rate of $2,035.93. Placement with APC 0112 would more closely comply with the two times rule. From the perspective of clinical and resource homogeneity, APC 0112 may not be the optimal group, but it is a reasonable interim step until adequate cost data would be collected for these CPT codes.

Baxter believes that the proposed HOPPS APC rates for G0267 are grossly inadequate and perpetuation of these rates in CY 2008 threatens Medicare beneficiary access to vital health services. This threat comes at a critical time in adult stem cell therapy innovation that will result in remarkable advances in patient care, not only for cancer but also for other life-threatening or disabling conditions.

Although Baxter believes that CMS's recognition of CPT codes 38210-38215 represents an important first step, it is likely to be insufficient to capture the full range of variability in cell processing services. We believe that CMS will find significant variation in median costs not only across these CPT codes, but also within specific codes. New procedures have been developed that generate different end products of cell depletion processes than are identified by the current CPT codes. These end products address a range of emerging clinical applications for stem cell transplantation procedures. In the future, a single CPT code, such as CPT 38210 may not be sufficient to report the various methods and end products of T-cell depletion.

Historically, CMS has recognized the complexities of setting payment rates for blood and blood products. Baxter recommends that CMS should continue to revisit reporting and payment for adult stem cell processing and transplant innovations. Appropriate payment will signal to the provider community the Administration's strong support of the emerging applications of adult stem cell treatments.

2. Packaging Drugs and Pharmaceuticals

CMS proposes to continue exempting the oral and injectable forms of 5HT3 anti-emetic products from packaging, Baxter agrees with CMS that the primary objective should be to continue to ensure that Medicare payment rules do not impede a beneficiary's access to anti-emetics so separate payment is desirable. It also fits with the objectives of the President's Executive Order 1340 to create comparable pricing structures (not rates) so that patients can compare the cost of different services across sites. Since anti-emetics are not bundled in the physician fee schedule, the proposal creates a comparable structure to compare copayment costs in different settings.

Unfortunately, beneficiaries will continue to have problems comparing prices between treatments in the physician setting and the hospital outpatient because drugs under $60 are bundled in the hospital outpatient prospective payment system. To the extent that private payers adopt these structures, it clutters the landscape for price comparisons in the private payer market, defeating the objectives of the Executive Order through failure to create a clear consistent platform for price transparency. Thus, Baxter recommends that these drugs be unbundled for the sake of transparency. We do not believe that unbundling drugs will cause hospitals to overuse drugs, such as Heparin, given it would be medical malpractice to do so.

3. Specified Covered Outpatient Drugs

For CY 2008, CMS proposes to pay for pharmaceuticals at Average Sales Price (ASP) plus 5%. CMS would also collect data on pharmacy overhead centers on an uncoded revenue center. CMS believes that ASP plus 5% is sufficient to include all acquisition costs and pharmacy overhead.

We do not understand why the CMS analysis concludes at variance with the sum of the conclusions of the extensive analyses conducted by Congressional support agencies. The Government Accountability Office (GAO) reported that actual acquisition costs for drugs is at ASP plus 3% for hospitals (October 31, 2005 letter to Chairmen of Finance, Ways and Means and Energy and Commerce.) CMS agrees with that analysis. The Medicare Payment Advisory Commission reports in the June 2005 Report to Congress that non-drug hospital pharmacy costs were roughly 26 percent to 28 percent of the total pharmacy costs. CMS does not dispute that result. This would suggest a higher number than ASP plus 5%. On the basis of the GAO report that showed wide and meaningless variation as a result of using the cost to charge ratio methodology for drug payment, Congress rejected the use of the claims data as a basis for payment. Why are the claims data continuing to be used by CMS as a ruler for determining adequate payment for drugs after an explicit rejection of these data by Congress?[4]

ASP plus 5% is particularly ill-suited for intravenous immune globulin (IVIG), and at an extreme, may pose a risk of disruption to access to IVIG in the "safety net" setting of the hospital outpatient department. The HHS Office of the Inspector General (OIG) report found that only 56 percent of IVIG sales to hospitals by the three largest distributors occurred at prices below the Medicare payment amount in the third quarter of 2006. And this "positive" result still means that 44 percent of hospital purchases to treat patients with IVIG were above ASP plus 6% (and the Assistant Secretary for Planning and Evaluation numbers for the prior quarter in its report showed even fewer hospitals being able to purchase IVIG at ASP plus 6% than the OIG data.[5]) One potential solution that CMS has initiated was the preadmission service; however, the data on charges for preadmission services for IVIG show a wide variation. Baxter believes that hospitals are not sure of the service content for the preadmission fee so that hospitals don't know the appropriate fee to charge related to the use of the drug. We appreciate CMS proposing to continue the preadmission fee but request that it remain at $71 while further education and refinement of the charge occurs.

Setting aside ASP plus 5%, one of the principal problems with the current HOPD system is CMS's lack of recognition through a dispensing fee or other mechanism of the services provided by clinical pharmacists in the more intensive hospital outpatient setting. Clinical pharmacists participate in all stages of the medication delivery process, including drug ordering, transcribing, dispensing, drug preparation, compounding, administering, and monitoring. Clinical pharmacists participate in direct patient care to address anemia, pain management,

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[4] Government Accountability Office (GAO), Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, September 2004.

[5] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV), February 2007

anticoagulation therapy, nausea and vomiting. In the HOPD setting, focusing on the dispensing activities that occur at a more clinically complex level in the hospital outpatient setting than the other ambulatory settings makes sense. At a minimum, improving the documentation of their efforts may provide more opportunities for improvements.[6] Thus, we ask that CMS consider asking hospitals to charge for these patient care activities and collect these data.

In summary, Baxter does not support ASP plus 5% in this setting and payment system because it doesn't cover acquisition costs for IVIG, nondrug pharmaceutical costs and the supervision of clinical pharmacists that is so critical for quality of care. CMS should continue to work with hospitals so that the appropriate charges for preadmission services and other pharmacy costs for hospitals can be captured and paid so that the rates are equitable across these types of services.

4. Service Specific Packaging Issues: A4306 disposable drug delivery system

Given the poor quality of the administrative data, Baxter supports the CMS proposal to continue A4306, which is a single use infusion pump, as a packaged supply for 2008. These are ambulatory medication delivery devices that are used to provide a slow, continuous, intravenous infusion of chemotherapy medications, instead of electro-mechanical infusion pumps. However, we agree with the commentator at the APC panel as noted in the Proposed Rule that the code is misreported. In the proposed rule, CMS states it is reported 1,773 times with a cost of $3 and 40% of the time with CT scans. Baxter sells approximately 100,000 of these pumps to hospitals a year, not including the sales of other manufacturers of single use pumps that are used for outpatient infusion. The range of costs is roughly $20 to $60, depending on the features, with the average sales price around $30 to $35. We are not aware of a clinical scenario where A4306 used as part of a CT scan. The data in the rule demonstrate that the code is used incorrectly, the charge is wrong and the volume is largely unreported. Perhaps there is confusion about what is a drug delivery system for purposes of this supply code or hospitals may be reporting the charge or cost for A4305, a less expensive pump that has a higher flow rate, which is primarily used by home care companies, much less so by hospitals.

Because CMS has asked hospitals to report charges for all services with HCPCs regardless of packaging, we would appreciate attention to education of hospitals so that these codes are used correctly and revenues better match expenses. Based on contact with several hospitals, we believe that part of the costs for these products may frequently be retained in Pharmacy or the OR, when it should be retained in the Supply cost center. Hospitals and CMS are working to correct the overstatement of the ratio of cost to charges (RCC) for supplies that reflects reporting expenses in the Operating centers associated with revenues in the Supply cost center, so correcting pumps may ameliorate a small part of the Supply RCC problem. While it is a relatively lower cost product, it is a not a low volume item.

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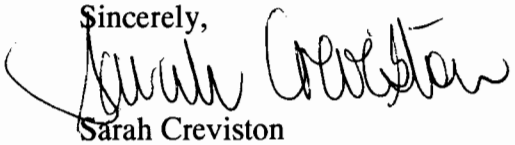
[6] "Evaluation of Clinical Pharmacy Services in a Hematology/Oncology Outpatient Setting," The Annals of Pharmacotherapy, August 2006, Shah, Dowell ad Greene

Since there are multiple problems with missing revenues, misreported or missing HCPCS codes, Baxter requests that CMS provide instructions for hospitals on the appropriate revenue center for this supply and contact the coding clinic about the need for better instructions about the HCPC code for this product.

Conclusion

In conclusion, Baxter appreciates this opportunity to comment on the Proposed Rule. Equitable payment requires continued attention to refinement and improvement of the hospital payment system will aid in ensuring the payment for one group of services as compared to another is not out of alignment. As a result, significant work remains to be done to refine the HOPPS ensure that reimbursement does not create access barriers to existing or future treatments. If you have any questions, please contact me at 202 508-8210 or at sarah_creviston@baxter.com.

Sincerely,



Sarah Creviston
Vice President, US Government Affairs

BEHAVIORAL HEALTH SERVICES

186-O
(6)

PALOMAR
POMERADO
HEALTH

September 12, 2007

Centers for Medicare & Medicaid Services
Dept of Health & Human Services
Attn: CMS – 1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir or Madam:

I am writing to respectfully request that reimbursement rates for Partial Hospitalization Programs (PHP) and Intensive Outpatient Programs (IOP) that serve the chronic mentally ill adult population NOT be reduced. I have worked with this population for many years and am convinced that if it weren't for these day psychotherapy programs many of these disenfranchised individuals would end up crowding the emergency rooms and psychiatric hospital inpatient units far more frequently. This would result in considerably greater costs charged to Medicare & Medicaid / Medi-Cal insurance companies than paying for cost-effective outpatient programs. Reducing the reimbursement rates by 24% in PHP and 17% in IOP would be so drastic that many programs would likely have to close their doors. These Outpatient programs serve to keep the most seriously mentally ill schizophrenic, bipolar and depressed patients from being hospitalized, and to allow them to function adequately to be able to live in the community, work part-time, attend school, and lead productive lives to the best of their ability. It is a privilege and joy to work with these patients and I am sincerely asking that you reconsider this rate reduction proposal so that our patients may continue to receive the outpatient psychotherapy treatment they so desperately need.

Sincerely,

Mona Hanna, MFT
CA Lic # MFC 40837
Care Clinician

125 Vallecitos de Oro Suite A San Marcos, CA 92069 Tel 760.739.2971 or 800.336.2000 Fax 760.510.8352
A California Health Care District

187-0
(10)

WOODCREST
HEALTHCARE, INC.
Community Mental Health Center

226 South Drive – Natchitoches, LA 71457
318.354.1188

September 14, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services\200 Independence Avenue
Washington, DC 20201

SUBJECT; CMS-1392-P-MEDICARE PROGRAM; PROPOSED CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CY 2008 PAYMENT RATES

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals that would adversely affect CMHC'S Partial Hospitalization Programs.

I am a patient in the Woodcrest Healthcare, Inc. Partial Program, in Natchitoches, Louisiana. If I were not in the Partial Hospital Program, I would have to be in a psychiatric hospital (I am sure that is much more expensive than the partial program). When you are in the hospital you do not have intensive training, education, and relapse prevention groups. All of these groups are available in the Partial Program at Woodcrest.

I am asking you not to make financial cuts to the Partial Hospitalization Programs because we would not have anywhere else to go for treatment if this facility closes.

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely, Kenton C. Owens

IRAAN GENERAL HOSPITAL

CARING FOR THE LIVES WE TOUCH

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September 10, 2007

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1392-P
Necessary Provider CAH's

To Whom It May Concern:

This letter serves as a response to the proposed rule published in the August 2, 2007 Federal Register regarding the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates. Iraan General Hospital is a small West Texas 13 bed Critical Access Hospital located in Pecos County. The closest tertiary hospitals are located within an 80-118 miles radius. Along with our community, we serve at least 60 miles of Interstate 10, other state highways, and portions of Crockett and Terrell Counties. With the Medicare cuts over the years and a declining population, we sought out to become a CAH in the year of 2000. Becoming a CAH has kept our doors open to provide necessary medical care to the surrounding community.

We would like to address the paragraph that states: "In the event that a CAH with necessary provider designation enters in a co-location arrangement after January 1, 2008, or acquires or creates an off-campus facility after January 1, 2008, that does not satisfy the CAH distance requirements in Section 485.610(c), we are proposing to terminate that CAH's provider agreement, in accordance with the provisions of Sections 489.53(a)(3)."

P.O. BOX 665
305 WEST 5TH
IRAAN, TX 79744

PHONE: 432-639-2575
FAX: 432-639-2664
patientcare@iraangeneral.com

Iraan General Hospital has been located in the same building for around 55 years. The community has grown up around the hospital leaving no room for expansion or housing any new services. Our interpretation of this proposal is such that it prohibits any additional growth of outpatient services to our community. Pecos County has been designated as a Medically Underserved Area and is considered a Frontier Area. Over the years, our EMS service has been a volunteer organization. Recently due to declining members, our community no longer has a local transfer group. We have to arrange for transfer agencies to come 80 miles to pick up our patients. The golden hour for critical patients goes to the way side. We may at some time in the near future have to take responsibility for housing a transfer service. We also have to use other buildings to house our clinics due to a lack of space within the hospital.

With the proposal above, it appears CMS would deny our critical access hospital future opportunities to provide additional outpatient services to the community where there are no other sources of healthcare services. Critical Access Hospitals were created for rural areas with low volumes of populations but it is apparent that the elimination of future growth of outpatient services would be another reason for that population to decline. Our goal is to maintain our population and offer quality healthcare so patients do not have to travel for distances.

The hospital board and staff have made a commitment to search out new opportunities to enhance the community's healthcare. We strongly recommend CMS to eliminate the termination of necessary provider for acquiring or creating off-campus facilities after January 1, 2008. Loosing our CAH necessary provider status for improving healthcare by placing it in an off-campus facility would be devastating to our area.

If you have any questions, or we can provide you with more information, please feel free to call or email.

Sincerely,

Teresa Callahan, CEO
Iraan General Hospital
P.O. Box 665
Iraan, Texas 79744
432-639-2575
tlcallahan@sbcglobal.net

St. LUKE'S HOSPITAL

189

September 13, 2007

Centers of Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P (NECESSARY PROVIDER CAH'S)
P.O. Box 8011
Baltimore, MD 21244-1850

RE: NECESSARY PROVIDER CAH'S

To Whom It May Concern:

This letter is to comment on the notice of proposed rulemaking for Hospital Outpatient Prospective Payment System (OPPS) that includes proposals specific to Critical Access Hospitals (CAH). This proposed rulemaking was published on July 16, 2007 and will be effective January 1, 2008 if implemented.

Saint Luke's Hospital converted to Critical Access Hospital status in September, 2005 under the necessary provider provision. This conversion allowed our hospital to remain a viable entity with a payor mix as high as 75% Medicare and 4% Medicaid. Conversion to Critical Access status given our case mix in a rural retirement community has allowed our hospital to continue to provide needed acute care services to the residents of Polk County, North Carolina.

I have serious objections to the provisions in the proposed rule which will eliminate the potential of a necessary provider, or any CAH, to establish a provider based department in a remote location or an off campus distinct part psychiatric or rehabilitation unit (on or after January 1, 2008) that does not meet the distance criteria for CAH from another hospital or CAH. The penalty for establishing such a unit can be the loss of CAH certification. This proposal has significant potential to create a negative situation for Saint Luke's Hospital. It will impact access to care for Medicare beneficiaries in our rural community.

We believe that potential access will be diminished in our rural community because we are experiencing a growing inability to recruit or retain physicians in private, non-provider based practices. We are considering a physical hospital integration strategy with our existing primary care physicians and new physicians being converted to provider based. Many hospitals are changing from a private practice model to an employment model under the control of the hospital. Over the last few years we have lost physicians from our community

101 Hospital Drive
Columbus, North Carolina 28722
(828) 894-3311

due to inability of the physicians to make competitive salaries even though they are productive. As we recruit new physicians, we are finding that the hospital needs to offer an employment arrangement in order to be competitive with other communities. The only way that we can sustain patient access to primary care providers is through provider based arrangements.

As you are aware, a strong primary care base in a community is needed to support other specialties such as general surgery, orthopedics, gynecology, ophthalmology, urology, gastroenterology, etc. Without that primary care base, significant erosion of access for our population would occur. Currently over 24 % of our county's population is over the age of 65. This lack of access would create an inability of many of our elderly adults to receive needed services.

We therefore recommend that you delete this provision.

With Best Regards,

Cameron Highsmith
President/CEO

CCH/ct

Wooddale
MENTAL HEALTH

190-0
(5)

September 12, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Subject: CMS-1392-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting Partial Hospitalization Programs. I am the Program Manager at Wooddale Mental Health in Baton Rouge, Louisiana.

Lack of facilities, trained professionals and inadequate reimbursement will make mental healthcare in Louisiana worse off than prior to the Hurricanes Katrina and Rita.

The proposed rate reduction in reimbursement for Mental Health services will severely limit agencies' ability to provide even the most limited services. This includes psychiatry and outpatient therapy, which is reimbursed at a rate that makes breaking even under the current reimbursement levels a challenge.

If the proposed rate cuts are implemented, there will be no way for residents to receive appropriate care. Many providers will go out of business; many residents will go without care.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to Partial Hospitalization Programs. As stated above, such provisions would be devastating!

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

Debbie Tullier
Program Manager

1335-B Wooddale Boulevard ✢ Baton Rouge, LA 70806 ✢ Email: cmhcwmh@bellsouth.net
Phone: 225.928.4969 ✢ Fax: 225.928.4983

191

Mercy
MEDICAL CENTER
CENTERVILLE
A member of Mercy Health Network

September 11, 2007

Leslie Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Ref: CMS—1392-P Medicare Program; Changes to the Hospital Outpatient Prospective Payment Systems and CY 2008 Payment Rates; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals; Proposed Rule (72 *Federal Register* 42628), August, 2 2007.

Dear Ms. Norwalk:

As one of Iowa's 82 Critical Access Hospitals (CAHs), Mercy Medical Center - Centerville is pleased to take this opportunity to provide comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the CY 2008 outpatient Prospective Payment System (PPS) published in the August 2, 2007 *Federal Register*.

Necessary Provider CAHs – Provider-Based Facilities of CAHs

Section 405 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ended states' authority to grant necessary provider designations and thereby waive the distance eligibility requirement for CAHs, effective January 1, 2006. CAHs certified as a necessary provider by January 1, 2006 were granted grandfathered status. Iowa's 82 CAHs were certified as necessary providers by the state.

This rule proposes that if a CAH operates a provider-based facility that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital. CMS' position is that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. CMS states termination could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

It appears as if CMS intends this proposal to apply to inpatient psychiatric or inpatient rehabilitation facilities (even though rehabilitation units are on the list for which provider-based determinations are not necessary). It is unclear if CMS intended to include rural health clinics (RHCs) and other clinics in this proposed policy. CMS should clearly state to which types of entity it intends to apply this policy.

We would oppose any attempt by CMS to apply the CAH 35-mile distance requirement to provider-based clinics of CAHs. Congress adopted the CAH program in 1997 with the intent of ensuring access to hospital services for Medicare beneficiaries in rural areas. Without the CAH program many rural Iowa hospitals would have faced closure with continued financial pressure from inadequate reimbursement under the Medicare program. Compounding Iowa's low Medicare reimbursement rates is Iowa's large percent of Medicare population; Iowa has the fourth highest percent of residents 65 years and older, and ties second in the nation for residents 85 years and older.

The Iowa health care system is on the brink of a physician supply crisis. This is a pervasive issue that affects the state as a whole. Relocation to other states is significant and is the principal reason for attrition from the supply of Iowa physicians, accounting for more than 60 percent of the annual loss, according to a University of Iowa's Carver College workforce report released in 2007. The physician shortage is a direct correlation to inadequate reimbursement from the Medicare program for both hospitals and physicians.

CAHs establish provider-based clinics for the very purpose of ensuring access to high quality care to the Medicare population, while at the same time trying to recruit the physicians necessary to provide the care. Without the provider-based relationships with these clinics, hospitals would not be able to reach out to neighboring clinics to provide local access to care to the many rural Iowa Medicare beneficiaries. The provider-based designation assists hospitals in recruiting and retaining Iowa's much needed physician work force.

Clear evidence of the rural nature of Iowa and the physician supply crisis is that Iowa has 148 RHCs. To be certified as a RHC it must be located in a rural area designated by the Bureau of the Census, and be designated either a medically underserved area; a geographic Health Professional Shortage Area (HPSA); or a population group HPSA. While the per visit limit for CAH-owned provider-based RHCs is waived, that is not unique to CAHs and is the case for any hospital with fewer than 50 beds. Physicians serving these clinics are often the only physician serving the service area for other types of care Medicare beneficiaries seek locally, e.g., hospice.

Clinics are often a way CAHs recruit physicians to practice in the area. By hiring a physician at one of the CAHs' provider-based clinics, the CAH guarantees that there is a physician in the area to serve on the medical staff. There are small communities in Iowa within 35 miles of a CAH that would have no physician without a RHC. As older physicians retire or younger physicians relocate, the ability to set up a RHC is critical to the continuation of basic medical care in rural areas. The hospitals that are impacted by this rule are small and rural by their nature and all of them already have trouble recruiting and retaining physicians. CMS should not make it even more difficult for CAHs to recruit and retain needed personnel.

The location of provider-based entities nearer to the next hospital than the CAH itself does not pose an unfair market advantages compared to neighboring hospitals. Surrounding PPS hospitals are able to locate their provider-based entities wherever they choose as long as they continue to meet the provider-based criteria. Thus, if anything, this policy would put CAHs at a distinct disadvantage compared to their local PPS counterparts.

If CMS implements this policy it will have broader affects on community access to care then CMS anticipates, and is contrary to CMS' repeated statement of intent of this proposal to "maintain hospital-level services in rural communities while ensuring access to care." CAH provider-based entities are located in different places for various reasons often unrelated to where the next hospital is located. While Medicare beneficiaries may be willing to travel a distance to a hospital for urgent/emergent care or services not available elsewhere, these patients want something closer to home for more routine visits, therapy, lab work etc. By forcing the CAHs to have all services on-campus, CMS will further exacerbate the geographical disparities to accessing high quality health care, and leave some Medicare beneficiaries without access to services.

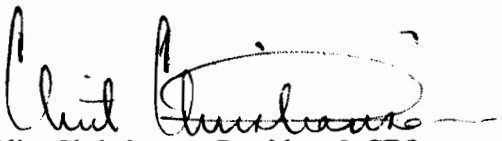
The implied "grandfather" provision that extends only to provider-based entities that maintain the same location will inappropriately lock them into outdated facilities. Some CAHs are operating provider-based entities in very old buildings that need to be replaced, which often means relocation. CAHs should not be discouraged from replacing these structures in order to improve patient safety and upgrade technology. Forcing physicians to continue to practice in outdated units and clinics at minimum serves to encourage them to practice elsewhere and could hinder access to needed primary care services.

Finalizing this provision with a January 1, 2008 effective date does not give providers enough time to adjust to this rule. Many hospitals are in the middle of planning or actively constructing new facilities. The financial viability of these projects revolves around provider-based status. Changing this requirement November 1, 2007 to a January 1, 2008 implementation is simply not reasonable or feasible. CMS should also provide clarification to its definition of "created or acquired after January 1, 2008" to exclude provider-based clinics that CAHs have begun the process of acquiring prior to January 1, 2008, given the lengthy process of seeking approval from CMS.

CMS should rescind this proposal altogether. It is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Such a policy would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas for Medicare beneficiaries.

Thank you for your review and consideration of these comments. If you have questions, please contact me at Mercy Medical Center – Centerville (641)437-3410.

Sincerely,



Clint Christianson, President & CEO
Mercy Medical Center – Centerville, Iowa

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VIA OVERNIGHT MAIL

September 13, 2007

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1392-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and Fiscal Year 2008 ; CMS-1392-P

Dear Sirs:

Munson Medical Center appreciates the opportunity to comment to the Centers of Medicare and Medicaid Services regarding the proposed rule updating the Medicare Outpatient Prospective Payment System for the Federal Year 2008, as published in the Federal Register.

Munson Medical Center is concerned about the accuracy of the data utilized for the new OPPS reimbursement schedules. These APC amounts have been revised and various services bundled together for future APC payment levels. However we believe that the data set is not a complete inclusion of all the costs involved in providing care. Claims for services that involve more than one procedure, that is the more complex cases, are excluded from these basing calculations since there's no way to assign incidental costs to one APC or the other. But, by excluding these claims, the true costs of these services are skewed..

Munson Medical Center is also concerned about the new requirement for reporting quality data to CMS, or face a 2% reduction in the payment formulas. Though Munson Medical Center recognizes the importance of continued quality initiatives, we are concerned about the short timeframe in which to implement necessary changes within the hospital in order to accurately report this information. Further, we are unsure of exactly what CMS is requesting of hospitals and which services are impacted. We suggest a deferment on the financial implications of this rule until the reporting data is more clearly defined and explained.

The payment for drugs and biologicals are also of great concern since we believe the reduction to the ASP plus 5% does not provide adequate reimbursement to cover drug acquisition and handling costs. This reduction could adversely affect our ability to provide important pharmaceutical therapies. The additional burden of identifying and separately reporting drugs and related overhead costs creates many operational difficulties and the accuracy of the resulting outcomes is questionable. We encourage CMS to recognize large difference in pharmacy overhead costs for different classes of drugs and reimburse hospitals accordingly.

The reduction to Partial Hospitalization is also of great concern to Munson Medical Center as this is already an underfunded service line that is proposed to receive even lower rates in FY 2008. It appears that this reduction amount was calculated using incomplete or inaccurate data which leaves the outcome in question. The proposed 23% reduction will cause many providers to re-assess their commitment to these needed outpatient psychiatric services. We ask that the current per diem payment levels of $234.73 be retained to compensate providers for the costs of these programs.

The payment for observation services and the limitation on payable circumstances is another issue facing Munson Medical Center. We believe that observation services are vital for determining appropriate treatment and whether to admit patients. To limit these services will create incentives to not provide this level of extended care. The payment of outpatient observation services is significantly less than inpatient DRG reimbursement should be used move expansively rather than diminished.

Munson Medical Center trusts it's concerns are adequately explained and complete, but if any questions arise, please feel free to contact me at (231) 935-6512 or our Reimbursement Manager, Steven Leach at (231) 935-7797.

Sincerely,

Edward B Carlson

Edward B. Carlson
Vice President and Chief Financial Officer

Robert H. Bea, CQE
Corporate Vice President
Regulatory and Quality Assurance

193

September 14, 2007

Mr. Kerry N. Weems, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore. MD 21244-1850

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

Dear Acting Administrator Weems:

Siemens Medical Solutions USA, Inc. welcomes the opportunity to provide comments on the proposed rules regarding the Hospital Outpatient Prospective Payment System and 2008 Payment Rates and the Ambulatory Surgical Center Payment System and 2008 Payment Rates.

Siemens Medical Solutions (Siemens), headquartered in Malvern, Pennsylvania and Erlangen, Germany, is one of the largest suppliers to the healthcare industry in the world. The company is known for bringing together innovative medical technologies, healthcare information systems, management consulting, and support services, to help customers achieve tangible, sustainable, clinical and financial outcomes. Siemens Medical Solutions employs approximately 31,000 people worldwide and operates in more than 120 countries.

Proposed Changes to CMS's Packaging Policies

While Siemens recognizes that CMS has previously implemented packaging policies for other selected ancillary services, we are concerned with the scope and methodology used in the Proposed Rule to eliminate separate payments for numerous ancillary or "dependent" radiology services by packaging those services into associated primary or "independent" services. CMS has not clearly defined the standards and thresholds used to determine when particular types of ancillary services are to be packaged into primary services. In the Proposed Rule, CMS indicates for example, that to identify imaging guidance codes, it conducted a broad search of the American Medical Association's CY 2007 book of CPT codes and the CY 2007 book of Level II HCPCS codes, using descriptor text to identify specific HCPCS codes as guidance codes to be packaged under the policy. We do not feel that this is an adequate basis for eliminating separate payment for a service. Additionally, due to an inadequate timeframe within which to analyze the existing claims data and to understand the impact, our ability to provide constructive comments to CMS regarding specific procedures has been limited.

We are also concerned that the current proposal may discourage use of clinically important services. For example, image guidance used in conjunction with radiation therapy procedures provides the ability to assess the patient anatomy and tumor status before, during and between treatment sessions to ensure maximum radiation dose is delivered to the tumor site while minimizing dose to healthy

Siemens Medical Solutions USA, Inc.
Customer Solutions Group

51 Valley Stream Parkway
Malvern, PA 19355

Direct: (610) 448-1736
Fax: (610) 448-1403
robert.bea@siemens.com

tissue. Implementation of a packaging policy may discourage oncologists from using image guidance during treatment planning and verification because of potentially inequitable payment for services. This would have a negative consequence for patient care if hospitals chose for economic reasons to not utilize such guidance in their treatment protocols to ensure safe and accurate clinical results for their patients.

Implementation of a packaging policy must be accomplished through a structured, well-defined and transparent process. We therefore request that CMS delay implementation of the new packaging policy and make publicly available the standards governing the packaging process, including the identification of which codes qualify for packaging, the rationale behind each decision, and the portion of the "independent" service APC payment rate that is associated with the packaged "dependent" service. Such a delay would provide an opportunity to verify whether a specific code properly falls within the definition of a "dependent" service, evaluate the clinical relationships between "dependent" and "independent" services, analyze the frequency with which a "dependent" service is associated with any given "independent" procedure, and assess the impact to payment rates. The availability of this information will also allow the healthcare industry to prepare for future packaged services and to determine proposed payment levels. Furthermore, CMS should educate and publish instructions to healthcare providers to ensure continued and correct coding of all services and charge data submission for packaged codes.

If CMS decides to implement the packaging policies as proposed for 2008, Siemens recommends that a threshold be established (i.e., a "floor") below which the payment level of any APC would not be permitted to drop. Without such a threshold, hospitals that perform a large number of these previously separately billed services may realize significant losses and potentially decrease access for patients and impact the quality of care.

Radiopharmaceuticals

Siemens disagrees with CMS' proposal to package payment for all diagnostic radiopharmaceuticals into diagnostic nuclear medicine procedures. Diagnostic radiopharmaceuticals have different clinical effect and cost features that would be masked by CMS' intention to pay for all under the same clinical APC. As such, they should be paid separately to account for their unique properties, acquisition costs and handling fees necessary for safe administration.

Packaging radiopharmaceuticals with the primary service APC may influence inappropriate use by providers. For example, physicians may select a radiopharmaceutical that is less costly versus selecting one that that is clinically most appropropriate for the patient's particular needs. As the demand for more effective and specific radiopharmaceutical innovations decreases due to this increased demand for less costly alternatives, future research and development may be stifled, ultimately impacting quality of patient diagnosis and care.

We also disagree with the agency's belief that hospitals have improved their reporting systems and that the line item cost for radiopharmaceuticals on claims forms is an accurate reflection of average acquisition, preparation, and handling costs for these products. Hospitals continue to have coding challenges as a result of billing systems that are not updated in a timely manner to accommodate code changes, and this potentially results in a failure to report radiopharmaceuticals separately in all cases. Thus, packaging of radiopharmaceuticals into nuclear medicine procedures creates an additional risk that data will be lost which is critical for future weighting and payment adjustments, resulting in improperly low payments. This may further encourage inappropriate use.

Additionally, CMS suggests that radiopharmaceuticals are "supplies" as opposed to "drugs" and are therefore eligible for packaging. We disagree. The Food and Drug Administration regulates radiopharmaceuticals as drugs. The Medicare OPPS statute also recognizes all radiopharmaceuticals (both diagnostic and therapeutic) as specified covered outpatient drugs (see Social Security Act Sec. 1833(t)(14)(B)(i)(I)). Therefore, there is no basis to treat radiopharmaceuticals differently from other specified covered outpatient drugs. Therefore, Siemens recommends that CMS treat all radiopharmaceuticals as drugs, entitled to separate payment and not subject to packaging.

Contrast Agents

Siemens disagrees with CMS' proposal to package all contrast agents into their associated independent diagnostic and therapeutic procedures. Contrast agents, like radiopharmaceuticals, are drugs and should be paid under the same methodology as other separately payable drugs.

Changes to Specific APCS:

PET/CT Scans

Siemens is concerned with CMS's proposal to move PET/CT CPT codes 78814, 78815, and 78816 from New Technology APC 1511 to the clinical APC 0308 which currently includes stand alone FDG PET codes. Given the differences in clinical impact to patient care, it is inappropriate to not distinguish between the clinical procedures performed with PET/CT and stand alone PET technology. PET/CT has emerged as one of the most important technologies used to manage cancer patients, and is an improvement over PET or CT scans alone. Patients benefit from PET/CT scans through earlier diagnosis, more accurate staging, precise treatment planning, and improved monitoring of therapy. The enhanced images generated by these scans allow physicians to pinpoint tumor position and detect cancer cells often well before they are readily visible. CMS is required to place CPT codes in APCs that are similar clinically, as well as on the basis of average resource use. PET/CT is not similar to stand alone PET in terms of resources used, and should not be grouped into the same stand alone FDG PET clinical APC. Siemens believes that CMS does not have sufficient, accurate, claims data to justify movement of these new technologies into the same clinical APC. The equipment costs associated with PET/CT are greater than for stand alone PET systems. To place both technologies in the same APC is to disadvantage PET/CT and the clinical advancements in patient care that the technology facilitates. Additionally, the technology will be further disadvantaged by CMS's proposal to package radiopharmaceuticals (e.g., FDG, which is commonly administered during nonmyocardial PET/CT and PET procedures). We therefore recommend that CMS place PET/CT codes 78814, 78815, and 78816 in a separate clinical APC from FDG PET which will ensure that both are appropriately reimbursed.

Myocardial PET Scans

As noted in our comments on the 2007 Proposed Rule, Siemens continues to believe that CMS's proposal to maintain multiple myocardial PET scans in the same APC as single myocardial PET scans significantly underpays providers for multiple scanning procedures. Multiple scans require greater hospital resources, as well as increased scan times, than single scans. The placement of both PET scans into one APC (APC 0307, $2677.71) results in underpayment for the facilities providing these resources.

As such, Siemens recommends that single and multiple myocardial PET scans be assigned to separate clinical APCs in 2008.

CT/CTA

Siemens agrees with CMS' proposal to assign the Cardiac CT and Cardiac CTA procedures to separate clinical APCs. We are concerned, however, about the adequacy of the payment rates assigned to these APCs (APT 0383 - $313.82 and APC 0282 = $105).

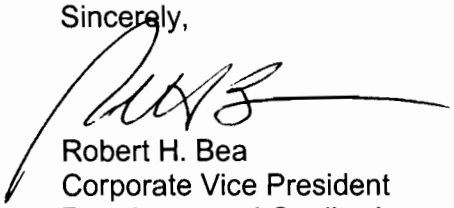
Siemens does not believe the claims data is sufficient for the establishment of a payment rate for APC 0383. Because the new category III "T" codes for Cardiac CT/CTA were not effective until January 1, 2006 and, given the delay in hospital billing systems to accommodate code changes, in addition to the fact that hospitals had been billing for cardiac CT/CTA procedures using other codes, we believe it likely that the claims upon which the proposed rates are based do not represent an entire year of claims history. Additionally, it is not clear whether the cost of contrast agents is included in the proposed rate. We therefore recommend CMS to continue to provide separate payment for contrast agents used in conjunction with all CT/CTA procedures, including cardiac CT/CTA.

Further, we recommend that CMS reconsider the APC classification for CPT 0144T and 0151T, which are proposed to be included in APC 0282 ("Miscellaneous CT"). Cardiac CTA requires more complex patient administration, more complex image processing, and increased interpretation time. Therefore, it does not appear to be clinically appropriate to include these codes in the same APC with the other limited CT studies that are included in APC 282.

*****

Thank you for your consideration of our request. Please contact me directly at (610) 448-1736 if you would like additional information with respect to our above comments.

Sincerely,



Robert H. Bea
Corporate Vice President
Regulatory and Quality Assurance
Compliance Officer
Siemens Medical Solutions USA, Inc.

NASMHPD National Association of State Mental Health Program Directors
66 Canal Center Plaza, Suite 302, Alexandria, VA 22314 (703) 739-9333 Fax (703) 548-9517

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September 14, 2007

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

Attention: CMS-1392-P

Subject: OPPS: Partial Hospitalization and other comments on OPPS

Dear Mr. Weems:

The National Association of State Mental Health Program Directors (NASMHPD) appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) regarding proposed payment for partial hospitalization programs (PHPs) that may be provided by a hospital to its outpatients or by a community mental health center (CMHC). Our comments are in response to "Medicare: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates" as published in the August 2, 2007, Federal Register.

NASMHPD represents the $27.3 billion public mental health service delivery systems serving 6.1 million people annually in all 50 states, four territories, and the District of Columbia. It is the only national association to represent state mental health commissioners/directors and their agencies. In addition, NASMHPD has an affiliation with the approximately 220 state psychiatric hospitals. Our members administer and manage community-based systems of care for the millions of individuals with serious mental illness who at times require immediate access to a variety of inpatient facilities and psychiatric units in general hospitals but are often cared for successfully on an outpatient basis.

NASMHPD commends the Centers for Medicare and Medicaid Services (CMS) for its long term efforts to structure a Medicare payment system that identifies the actual cost of providing services and pays for those services on a fair and equitable basis. The analysis done by CMS on the mapping of revenue codes in hospital-based programs is recommended for PHPs in CMHCs to more accurately reflect the costs of paying for these services. Similarly, the rate for group

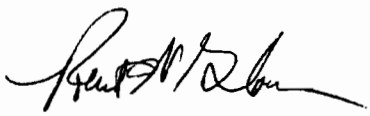
psychotherapy and other psychiatric ambulatory payment classification (APC) groups should cover the costs of delivering these services. Unless these services are paid at a rate that reflects the cost of providing them, more costly services such as PHP or hospitalization could be utilized.

The proposed decreases in payment for PHPs does not in our view reflect the actual changes in the cost of providing these services and could jeopardize their availability. Medicare payment policy should *create incentives for the highest quality of care to be delivered in the most appropriate and cost effective setting.* Partial hospitalization programs offer an excellent option for those individuals who do not require the level of intensity provided in an inpatient setting but need an array of services that are most efficiently and effectively provided in a partial hospitalization program. Partial hospitalization programs provide continuity of care for individuals being discharged from the hospital and also allow for shorter stays in the inpatient setting. Additionally, PHPs provide a cost effective alternative to inpatient hospitalization.

The multi-year decreases in payment for PHPs have already resulted in the closing of numerous community mental health center programs, placing additional stress on the overloaded inpatient hospital system. If the proposed 24 percent reduction in reimbursement for CY 2008 is adopted, it will have a devastating impact on PHPs and the other acute care providers such as emergency departments that will experience increased demand. NASMHPD recommends that the PHP rate remains at least at the $233 per day level, ensuring that clinically appropriate services are continued. PHPs are vital in providing a continuum of care that reduces hospitalizations and provides services that meet the needs of individuals who have severe mental illnesses.

NASMHPD strongly opposes these proposed cuts at a time when there is a deficit in acute care inpatient services of crisis proportions and encourages CMS to keep the current rate for PHP constant for CY 2008. We recommend that CMS convene a representative group of mental health providers and other experts to examine the current payment methodology and recommend improvements that ensure the availability of high-quality services at the most appropriate and cost effective level of care.

Sincerely,



Robert W. Glover, Ph.D.
Executive Director

Behavioral Health Services

CAPE COD HEALTHCARE

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September 12, 2007

Mr. Herb Kuhn, Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: CMS-1392-P: Proposed Changes to Hospital Outpatient PPS

Dear Mr. Kuhn:

On behalf of Cape Cod Hospital (CCH), a not-for profit, sole-community provider of a wide range of healthcare services, I appreciate the opportunity to comment on a proposed 41 % reduction in reimbursement for partial hospitalization services over a three year period beginning with a 24 % reduction for calendar year 2008.

Cape Cod Hospital offers the full continuum of care in its behavioral health service line. CCH takes pride in its ability to continue to offer full inpatient, partial hospitalization and outpatient behavioral health services to the residents and visitors of Cape Cod. Medicare is our largest third party payer as it covers fully 25 % of our partial hospitalization program participants.

However, Cape Cod Hospital experiences operating losses from this service line. These losses will increase given the direct reductions proposed for partial hospitalization services. Moreover, we believe that such a reduction would place our ability to offer a financially viable partial program in jeopardy. Should we have to close the partial program, our emergency room and our inpatient program would be deleteriously affected as there would be no service offering for those patients who need treatment that falls somewhere between occasional outpatient services and a full-fledged admission. The lengths of stay on our inpatient unit would increase. The continuum of care would thus be seriously disrupted without the partial program as a step-down option. We believe that in the long-term additional costs would be added to the behavioral healthcare system as care

The Psychiatric Center at Cape Cod Hospital
P.O. Box 640, 27 Park Street
Hyannis, MA 02601
toll free 1.800.545.5014
main 508.862.5566
fax 508.775.1598

Cape Cod Human Services
460 West Main Street
Hyannis, MA 02601
toll free 1.800.894.2247
main 508.790.3360
fax 508.790.3366

would be delivered in the more expensive settings of emergency rooms and longer stays in inpatient beds.

These arguments are all the more pressing because CCH offers the only full spectrum behavioral health treatment option for inpatient and partial hospitalization services on Cape Cod. Recently, the other local partial program on the Cape closed precipitously. Our belief is that increased demand for services will be placed on our partial program as a result. Decreased reimbursement would indeed exacerbate pressures on an already financially strapped service line facing a sudden increase in demand.

We strongly urge CMS to keep the PHP rates at their current level and to forego planned cuts in PHP reimbursement for 2008 and beyond.

Thanks you for the opportunity to offer these comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Carol Plotkin

Carol Plotkin, LICSW
Executive Director
Behavioral Health Services Cape Cod Healthcare Inc.

cc: Stephen L. Abbott, CEO
Stephen J. Guimond, CFO
Jeffrey S. Dykens, Corporate Controller
James Poole, Director of Managed Care and Reimbursement